From:	Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]
Sent:	8/14/2018 1:29:27 PM
To:	Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]
Subject:	KEI Vizamyl Response
Attachments:	dft response 08132018.docx

Dear Dale and Mark:

I have attached my draft reply to Ms. Cassidy at KEI requesting a follow-up phone call. Please send me your edits so it can be finalized through Ex. Sec.

Thanks.

Ann

--
Ann M. Hammersla, J.D.
Director
Division of Extramural Inventions and Technology Resources
Office of Policy for Extramural Research Administration
Rockledge 1, Suite 310
6705 Rockledge Drive
Bethesda, Maryland 20892-7974
PHONE: 301-435-0745

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

b5

From: Bradley, David (NIH/NIDCR) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4232AB2D5334498BA86ABBCEC1E39784-BRADLEYDA]
Sent: 8/28/2017 2:08:25 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: Automatic reply: KEI Request FOIA Request Re: CRADAs Executed 2010-2017

I am out of the office Aug 28 through Sept 1. I will respond to your email as soon as possible. For assistance with new agreement requests, contact Fernando Ponce at poncef@nidcr.nih.gov to establish a tracking number. Contact Yun Mei at yun.mei@nih.gov for assistance with new Employee Invention Reports or licensing agreements. For MTAs or CRADAs, contact Lawrence Wu, wuz4@nidcr.nih.gov.

From: Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]
Sent: 6/24/2019 7:03:13 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Pazman, Cecilia (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf35741501e247d887acd224eaf9d679-pazmance]; Kirby, Tara (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2368a591fa4c4932a802e5d467fb49ed-tarak]
Subject: RE: Inquiry regarding 84 FR 28063 Doc 2019-12708 - Prospective Grant of Exclusive Patent License: Lutetium-177 Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors

Ok will do.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, June 24, 2019 15:03
To: Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Cc: Pazman, Cecilia (NIH/NHLBI) [E] <pazmance@nhlbi.nih.gov>; Kirby, Tara (NIH/NIAID) [E] <tara.kirby@nih.gov>
Subject: Re: Inquiry regarding 84 FR 28063 Doc 2019-12708 - Prospective Grant of Exclusive Patent License: Lutetium-177 Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors

b5

Thanks

Please send me a copy of the final so I can track these Qs and As

Sent from my iPhone

On Jun 24, 2019, at 11:57 AM, Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov> wrote:

> b5
>
> **From:** Rohrbaugh, Mark (NIH/OD) [E]
> **Sent:** Monday, June 24, 2019 14:56

To: Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Cc: Pazman, Cecilia (NIH/NHLBI) [E] <pazmance@nhlbi.nih.gov>; Kirby, Tara (NIH/NIAID) [E] <tara.kirby@nih.gov>
Subject: Re: Inquiry regarding 84 FR 28063 Doc 2019-12708 - Prospective Grant of Exclusive Patent License: Lutetium-177 Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors

I would like to see the draft please

Sent from my iPhone

On Jun 24, 2019, at 10:14 AM, Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov> wrote:

> Mark- b5
> b5
>
> Thanks !
>
> ---
>
> **From:** "Claire Cassedy" <claire.cassedy@keionline.org>
> **Date:** Monday, June 24, 2019 at 12:33:19
> **To:** "Shmilovich, Michael (NIH/NHLBI) [E]" <michael.shmilovich@nih.gov>
> **Subject:** Inquiry regarding 84 FR 28063 Doc 2019-12708 - Prospective Grant of Exclusive Patent License: Lutetium-177 Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors
>
> Dear Mr. Shmilovich,
>
> I am writing in reference to the Federal Register notice (84 FR 28063 Doc 2019-12708) regarding, "Prospective Grant of Exclusive Patent License: Lutetium-177 Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors," for which you are listed as the contact for inquiries. I was hoping you could provide me with some further information regarding the status of the technologies.
>
> 1. At what stage of development are the inventions listed?
> 2. Has the government funded any clinical trials relevant to these technologies?
> 3. If the government has provided funding, how much has been spent by the government on these trials? Can you provide NCT numbers?
> 4. How many years of exclusivity have been offered in this agreement, and what will the royalty rate be?
> 5. Regarding the company to receive the licenses, Molecular Targeting Technologies, Inc. are any former NIH employees associated with the company?
>
> Thank you in advance for your assistance in this matter.
>
> Best Regards,
> Claire Cassedy
>
> --
> Claire Cassedy
> Knowledge Ecology International
> 1621 Connecticut Avenue NW
> Suite 500
> Washington, DC 20009

Tel.: 1.202.332.2670

From: Wolinetz, Carrie (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=WOLINETZCDC9A]
Sent: 10/11/2016 5:38:54 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: FW: Heads up: Draft House letter to POTUS mentioning NIH/March-In

FYI

From: Hallett, Adrienne (NIH/OD) [E]
Sent: Wednesday, October 05, 2016 5:35 PM
To: NIH Director's Executive Committee
Subject: Heads up: Draft House letter to POTUS mentioning NIH/March-In

Draft letter to POTUS that Rep. Pocan is circulating about drug pricing. It offers three potential strategies to address the topic with NIH/Bayh-Dole listed first. 26 signers now with deadline Friday.

The President Can Act Against Drug Company Rip-Offs. These House Dems Explain.
10/05/2016 03:05 pm ET

Richard (RJ) Eskow Host, The Zero Hour; Sr. Fellow, Campaign for America's Future

Rep. Mark Pocan speaks with Richard Eskow on The Zero Hour

This week I spoke with Rep. Mark Pocan (D, WI) about an open letter to President Obama he is circulating to fellow members of Congress this week. It's an important letter, not only for its subject matter - it addresses our current crisis in runaway drug costs - but because it explains how the White House can address this issue without the need to pass legislation in the Republican-controlled House.

Most of us already know we've got a problem. A Kaiser survey released last week shows that 77 percent of Americans believe that "prescription drug costs are unreasonable."

They're right. As the letter notes, Gilead Sciences recently set a price of $84,000 for its 12-week course of Hepatitis C treatment - even though, as activist Annette Gaudino explained last August on The Zero Hour, it charges a fraction of that cost in other countries and still turns a profit. The letter also attacks the "price-gouging and anti-competitive behavior" of Mylan Pharmaceuticals, which jacked up the price of an EpiPen by nearly 500 percent over a five-year period.

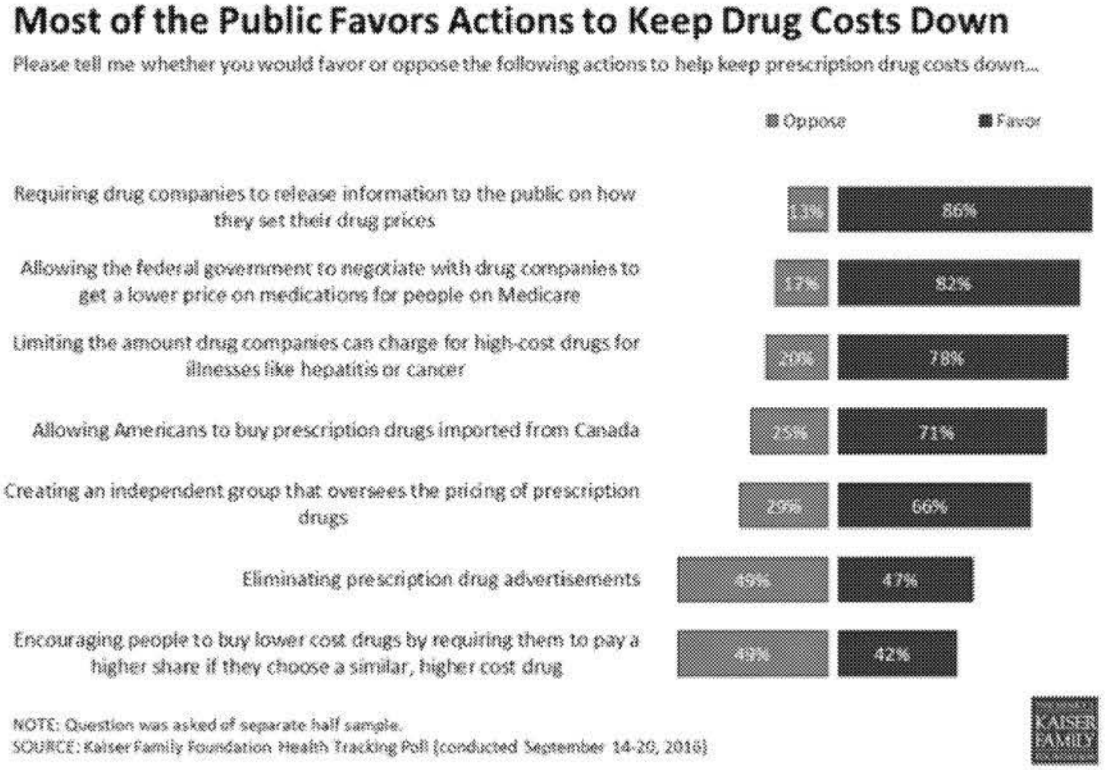
Rep. Pocan's letter urges President Obama to "use executive action and take concrete steps" to address the drug cost crisis, and lists three tools that the president can use. The first is the Bayh-Dole Act, which gives the National Institutes of Health the power to ensure that medications that were developed at taxpayer expense are accessible to the public at affordable rates.

Next, the president can use the authority granted to the Secretary of Health and Human Services, under the Medicare Drug Act of 2003, to allow the importation of lower-cost drugs from other countries under certain conditions.

Lastly, the president to direct the Federal Trade Commission to stop drug companies' monopolistic practices, especially when drug patent holders pay generic companies to delay lower-cost alternatives to market - a practice that is sometimes called "pay for delay."

Most Americans already support strong action to rein in drug prices. The Kaiser survey showed, for example, that 82 percent of those polled support allowing the Federal government to negotiate drug prices and 71 percent support allowing Americans to purchase drugs imported for Canada.

Figure 13



Most of the Public Favors Actions to Keep Drug Costs Down

Please tell me whether you would favor or oppose the following actions to help keep prescription drug costs down...

NOTE: Question was asked of separate half sample.
SOURCE: Kaiser Family Foundation Health Tracking Poll (conducted September 14-20, 2016)

The Pocan letter is supported by a number of activist groups, including Social Security Works, People's Action, CREDO Action, and a number of other organizations. (See complete list below.)

A number of Democratic House members have signed Rep. Pocan's letter. (No Republicans have signed it, which is telling: The Bayh-Dole Act was a bipartisan piece of legislation, which seems unimaginable today.) They are listed below.

If your Representative's name isn't on the list, they have until Friday to sign it. This would be a good time to call their office and suggest that they do.

***Groups Supporting the letter**: CREDO Action, Social Security Works, People Demanding Action, the Other 98%, Courage Campaign, Progressive Congress, Blue America, Public Citizen, Knowledge Ecology International (KEI), Daily Kos, Public Leadership Institute, People's Action, and the Universities Allied for Essential Medicine.*

(Note: I am affiliated with People's Action; Social Security Works sponsors The Zero Hour radio program on We Act Radio.)

***House members who have signed the letter as of this writing**:*

Lloyd Doggett
Jan Schakowsky
Keith Ellison

Raul Grijalva
Nydia M. Velázquez
Elijah E. Cummings
Jim McDermott
Alan Lowenthal
Jared Huffman
Luis Gutiérrez
Eleanor Holmes Norton
Sam Farr
Rosa DeLauro
Gwen S. Moore
John Conyers, Jr.
Earl Blumenauer
Barbara Lee
Maxine Waters
Steve Cohen
Brenda L. Lawrence
Michelle Lujan Grisham
John Yarmuth
Donna F. Edwards
Emanuel Cleaver
Peter Welch

From: Rogers, Karen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B23EF4CA2FA14A6EB174EE611953A396-ROGERSK]
Sent: 6/6/2018 8:47:09 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Hammersla, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87fb28aa23744c0b855ef0683ac2e8b4-hammerslaa]
Subject: FW: Legal/regulatory restrictions on transfers of NIH-funded IP

Hi Mark – Heard that you requested that all of the inquiries from KEI be sent to you. Please see below. Regards, Karen

From: James Love [mailto:james.love@keionline.org]
Sent: Wednesday, June 06, 2018 2:40 PM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>; Ferriter, Karin <Karin.Ferriter@uspto.gov>
Cc: Andrew Goldman <andrew.goldman@keionline.org>; robert.silverman@oxfam.org; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: Re: Legal/regulatory restrictions on transfers of NIH-funded IP

Dear Karen Rogers,

In case it was not explained before, we are interested in knowing if the NIH has a policy that would prevent a company from transferring an NIH funded license to an entity in order to avoid paying U.S. income taxes.

Are you saying that the NIH has no interest in regulating transactions that allow patent holders of NIH funded inventions to evade U.S. income taxes on inventions, or are you saying that you don't want to talk to us? Or both?

Jamie

On Wed, Jun 6, 2018 at 8:24 PM, Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov> wrote:

> Dear Mr. Goldman – Thank you for your inquiry.
>
> We don't have any interest in such a discussion and I'm afraid that we don't have any suggestions for a different office at NIH that would. Regards, Karen
>
> *Karen L. Rogers*
>
> *Acting Director*
>
> *Office of Technology Transfer*
>
> *National Institutes of Health*

6011 Executive Boulevard, Suite 325

Rockville, MD 20852

From: Andrew Goldman [mailto:andrew.goldman@keionline.org]
Sent: Monday, May 07, 2018 4:11 PM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Cc: robert.silverman@oxfam.org; Jamie Love <james.love@keionline.org>
Subject: Legal/regulatory restrictions on transfers of NIH-funded IP

Dear Karen, Ann:

I have cc'd Robert Silverman of Oxfam, and James Love of KEI, as we had hoped to have a conversation with you regarding the NIH's authority to restrict offshore transfers of NIH-funded intellectual property from a company to a subsidiary or affiliate.

Would you have time for a phone call on this? If there is a different office in NIH that you think would be more appropriate for this conversation, please let us know.

Kind regards,

Andrew S. Goldman

Counsel, Policy and Legal Affairs

Knowledge Ecology International

andrew.goldman@keionline.org // www.twitter.com/ASG_KEI

tel.: +1.202.332.2670

www.keionline.org

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,
twitter.com/jamie_love

From: Mowatt, Michael (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB1EF7E2E54B4164AE34814574BDA638-MMOWATT]
Sent: 11/22/2017 4:21:13 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: Near final draft
Attachments: HHS Zika Update Memo DRAFT 171122 CLEAN.docx

Close hold please

Mark,

Here is a memo we've drafted to update Tony, b5 on our licensing efforts.

Comments?

Thanks,

Mike
Michael R. Mowatt, Ph.D.
Director, Technology Transfer and Intellectual Property Office

National Institute of Allergy and Infectious Diseases
National Institutes of Health
U.S. Department of Health and Human Services

+1 301 496 2644

National Institute of
Allergy and
Infectious Diseases

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b5

b5

From: Tong, Betty (NIH/NIDDK) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D17F99D0A02B44B89429099F24AA1D71-TONGB]
Sent: 8/31/2017 3:30:55 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Rogers, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b23ef4ca2fa14a6eb174ee611953a396-rogersk]
CC: Deutch, Alan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=244d755700584812af36b5e787285647-deutcha]; Niebylski, Charles (NIH/NIDDK) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3248b0e1497e439b94ce47c2f52b0268-niebylskicd]; Goldstein, Bruce (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb67e8fe5aa2452a8a7f200e5fb4335b-goldsteb]; Shmilovich, Michael (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dfe19bfd1d443ceb700b9f22d159a90-shmilovm]
Subject: RE: Vital Spark

Thanks Mark, **b5** Betty

Betty B. Tong, Ph.D.
Senior Licensing and Patenting Manager
Technology Advancement Office
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
12A South Drive, Suite 3011
Bethesda, MD 20892

Phone: (301) 451-7836
Email: tongb@mail.nih.gov

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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, August 30, 2017 5:37 PM
To: Tong, Betty (NIH/NIDDK) [E] <tongb@mail.nih.gov>; Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>
Cc: Deutch, Alan (NIH/NHLBI) [E] <deutcha@nhlbi.nih.gov>; Niebylski, Charles (NIH/NIDDK) [E] <charles.niebylski@nih.gov>; Goldstein, Bruce (NIH/OD) [E] <goldsteb@mail.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Subject: RE: Vital Spark

b5

From: Tong, Betty (NIH/NIDDK) [E]
Sent: Wednesday, August 30, 2017 9:35 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>

Cc: Deutch, Alan (NIH/NHLBI) [E] <deutcha@nhlbi.nih.gov>; Niebylski, Charles (NIH/NIDDK) [E] <charles.niebylski@nih.gov>; Goldstein, Bruce (NIH/OD) [E] <goldsteb@mail.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Subject: FW: Vital Spark

Dear Mark, Karen,

We have a new inquiry from KEI, please see the email string below. Alan would like to include both of you in the loop for a coordinated response.

Thanks for any advice in advance.

Best regards,
Betty

Betty B. Tong, Ph.D.
Senior Licensing and Patenting Manager
Technology Advancement Office
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
12A South Drive, Suite 3011
Bethesda, MD 20892

Phone: (301) 451-7836
Email: tongb@mail.nih.gov

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From: Deutch, Alan (NIH/NHLBI) [E]
Sent: Wednesday, August 30, 2017 9:30 AM
To: Tong, Betty (NIH/NIDDK) [E] <tongb@mail.nih.gov>; Goldstein, Bruce (NIH/OD) [E] <goldsteb@mail.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Cc: Niebylski, Charles (NIH/NIDDK) [E] <charles.niebylski@nih.gov>
Subject: RE: Vital Spark

Thank you Betty. Are you sure you don't wish to continue supporting NIAAA?

Please loop in Mark R. and Karen R. so that all have the same information for a coordinated response.

Alan

From: Tong, Betty (NIH/NIDDK) [E]
Sent: Wednesday, August 30, 2017 9:24 AM
To: Goldstein, Bruce (NIH/OD) [E] <goldsteb@mail.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>
Cc: Niebylski, Charles (NIH/NIDDK) [E] <charles.niebylski@nih.gov>; Deutch, Alan (NIH/NHLBI) [E] <deutcha@nhlbi.nih.gov>
Subject: FW: Vital Spark

Good morning Bruce,

We received the following email from KEI and I wonder if OTT MEU has any suggestions of how to respond to them. As Misha/NHLBI OTTAD will be taking over NIAAA's P&L portfolios in a month in October, I hereby copy him and Alan as well as a heads up.

Misha, the license in question is A-034-2016, executed couple of months ago. b5 b5 and I forwarded earlier relevant emails to you on Monday. If any further questions, please let me know.

Thanks in advance for any suggestions Bruce.

Best regards,
Betty

Betty B. Tong, Ph.D.
Senior Licensing and Patenting Manager
Technology Advancement Office
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
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Email: tongb@mail.nih.gov

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From: jamespackardlove@gmail.com [mailto:jamespackardlove@gmail.com] **On Behalf Of** Jamie Love
Sent: Tuesday, August 29, 2017 3:04 PM
To: Tong, Betty (NIH/NIDDK) [E] <tongb@mail.nih.gov>
Subject: Re: Vital Spark

Thanks. It is my understanding that a standard NIH license includes various working requirements, and that the licenses can be terminated if those benchmarks are not met. Does the NIH have a database that keeps track of which licenses are granted, whether or not the licenses make the benchmarks, and if they are terminated for failures to work the patent sufficiently or other issues?

Jamie

On Tue, Aug 29, 2017 at 2:54 PM, Tong, Betty (NIH/NIDDK) [E] <tongb@mail.nih.gov> wrote:

> Yes.
>
> **Betty B. Tong, Ph.D.**
>
> Senior Licensing and Patenting Manager
>
> Technology Advancement Office
>
> National Institute of Diabetes and Digestive and Kidney Diseases
>
> National Institutes of Health

12A South Drive, Suite 3011

Bethesda, MD 20892

Phone: (301) 451-7836

Email: tongb@mail.nih.gov

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From: jamespackardlove@gmail.com [mailto:jamespackardlove@gmail.com] **On Behalf Of** Jamie Love
Sent: Tuesday, August 29, 2017 10:23 AM
To: Tong, Betty (NIH/NIDDK) [E] <tongb@mail.nih.gov>
Subject: Vital Spark

Hi, was this license ever issued?

https://www.federalregister.gov/documents/2016/04/19/2016-08985/prospective-grant-of-exclusive-license-development-of-the-cb1inos-series-of-compounds-as-a

--

James Love. Knowledge Ecology International
http://www.keionline.org/donate.html

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, twitter.com/jamie_love

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, twitter.com/jamie_love

From: Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent: 6/24/2019 7:26:48 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]
Subject: RE: Inquiry regarding 84 FR 28063 Doc 2019-12707 - Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer

Thanks Mark. I will make the correction.

Andy

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, June 24, 2019 3:00 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: Re: Inquiry regarding 84 FR 28063 Doc 2019-12707 - Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer

Regarding the last one, b5

b5

Sent from my iPhone

On Jun 24, 2019, at 9:59 AM, Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

> Hi Mark and Richard,
>
> My proposed responses to KEI are included below. Please let me know if you have any concerns.
>
> Thank you,
>
> Andy
>
> **From:** Claire Cassedy <claire.cassedy@keionline.org>
> **Sent:** Monday, June 24, 2019 12:33 PM
> **To:** Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
> **Subject:** Inquiry regarding 84 FR 28063 Doc 2019-12707 - Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer
>
> Dear Mr. Burke,
>
> I am writing in reference to the Federal Register notice (84 FR 28063 Doc 2019-12707) regarding, "Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer," for which you are listed as the contact for inquiries. I was hoping you could provide me with some further information regarding the status of the technologies.
>
> 1. At what stage of development are the inventions listed?

b5

2. Has the government funded any clinical trials relevant to these technologies?

b5

3. If the government has provided funding, how much has been spent by the government on these trials? Can you provide NCT numbers?

b5

4. How many years of exclusivity have been offered in this agreement, and what will the royalty rate be?

b5

5. Regarding the company to receive the licenses, Tailored Therapeutics, LLC are any former NIH employees associated with the company?

b5

Thank you in advance for your assistance in this matter.

Best Regards,
Claire Cassedy

--
Claire Cassedy
Knowledge Ecology International
1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
Tel.: 1.202.332.2670

From: Culhane, Ned (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=CULHANEE]
Sent: 9/28/2016 11:20:52 AM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
CC: Berkson, Laura (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Damianold]
Subject: Revised CRS report on March-In
Attachments: R44640_2016-09-23 CRS March-In Rights Under the Bayh-Dole Act.pdf

Good morning, Mark and Ann,

CRS has issued an updated report about the March-In Under the Bayh-Dole Act. I wanted to make sure you had the latest.

Ned

March-In Rights Under the Bayh-Dole Act

John R. Thomas
Visiting Scholar

September 23, 2016

Congressional Research Service
7-5700
www.crs.gov
R44640

CRS REPORT
Prepared for Members and
Committees of Congress

Summary

Congress approved the Bayh-Dole Act, P.L. 96-517, in order to address concerns about the commercialization of technology developed with public funds. This 1980 legislation awards title to inventions made with federal government support if the contractor consists of a small business, a university, or other non-profit institution. A subsequent presidential memorandum extended this policy to all federal government contractors. As a result, the contractor may obtain a patent on its invention, providing it an exclusive right in the invention during the patent's term. The Bayh-Dole Act endeavors to use patent ownership as an incentive for private sector development and commercialization of federally funded research and development (R&D).

The federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights," codified at 35 U.S.C. §203. March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself.

No federal agency has ever exercised its power to march in and license patent rights to others. In particular, the National Institutes of Health (NIH) has received six march-in petitions and has denied each one. A 2016 exchange of correspondence between Members of Congress and the Department of Health and Human Services suggests a difference of views related to agency authority under the march-in provision. Supporters of the use of march-in rights assert that they provide an unused mechanism for combatting high drug prices and ensuring that U.S. citizens enjoy the benefits of public R&D funding. Others assert that march-in rights do not provide such a broad authority, but rather are limited to four circumstances identified in the statute. They are also concerned that use of march-in rights might discourage private investment in the often considerable effort needed to bring early-stage technologies to the marketplace.

Congress possesses a number of options with respect to march-in rights. If the current situation is deemed acceptable, then no action need be taken. Congress could also consider amending the Bayh-Dole Act by specifying in greater detail the precise circumstances in which march-in rights should be exercised. Congress may also take such steps as transferring authority over the administration of march-in rights, requiring government contractors to submit periodic reports regarding the commercialization of inventions achieved through public funding, creating a centralized database of inventions subject to the Bayh-Dole Act, and taking steps to ensure that patents on inventions developed through government funding are licensed to the most capable enterprise.

Contents

Introduction 1
The Patent System: An Overview 2
  The Mechanics of the Patent System 2
  Patents and Innovation Policy 3
The Bayh-Dole Act 5
March-In Rights 7
  The Mechanics of March-In Rights 7
  March-In Petitions 8
  Debate over March-In Rights 10
Congressional Issues and Options 12
Concluding Observations 13

Contacts

Author Contact Information 14

Introduction

Congressional interest in facilitating U.S. technological innovation led to the passage of P.L. 96-517, Amendments to the Patent and Trademark Act.[1] This legislation is commonly referred to as the "Bayh-Dole Act,"[2] after its two primary sponsors, former Senators Robert Dole and Birch Bayh. This 1980 legislation awards title to inventions that government contractors make with federal government support, if the contractor consists of a small business, a university, or other non-profit institution. A subsequent presidential memorandum extended this policy to all federal government contractors.[3] As a result, the contractor may obtain a patent on its invention, providing it with an exclusive right in the invention during the patent's term. The legislation is intended to use patent ownership as an incentive for private sector development and commercialization of federally funded research and development (R&D).

The federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit.[4] The Bayh-Dole Act also provides federal agencies with "march-in rights." [5] March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself.

Members of Congress have recently taken note of the fact that march-in rights have never been exercised during the 35-year history of the Bayh-Dole Act.[6] In particular, the National Institutes of Health (NIH) has received six march-in petitions and has denied each one. A 2016 exchange of correspondence between some Members of Congress and the Department of Health and Human Services has suggested a potential difference of views about the appropriate use of march-in rights. [7] Some observers believe that march-in rights should be rarely, if ever invoked due to the significant investment the private sector investment may make to bring early-stage inventions into practical application. These commentators further assert that the use of march-in rights would discourage private enterprise from investing in the commercial development of any invention funded in part by the government. [8] On the other hand, others believe that U.S. taxpayers should be protected from what they view as excessive profiteering on technologies developed with public funding. They consider march-in rights to constitute a long-available, but entirely unused mechanism for combatting the high and growing cost of health care.[9]

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[1] 94 Stat. 3015 (1980). For further information about this legislation, see CRS Report RL32076, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*, by Wendy H. Schacht.

[2] See, e.g., Fred Reinharta and Stephen J. Susalkaa, "Inspired Bayh-Dole Act Turns 35," *les Nouvelles*, vol. 51 (March 2016), p. 17.

[3] See Memorandum on Government Patent Policy from President Ronald Reagan, to Heads of Executive Departments and Agencies, February 18, 1983, http://www.presidency.ucsb.edu/ws/index.php?pid=40945&st=&st1=.

[4] 35 U.S.C. §202(c)(4).

[5] 35 U.S.C. §203.

[6] See, e.g., William O'Brien, "March-In Rights Under the Bayh-Dole Act: The NIH's Paper Tiger?," *Seton Hall Law Review*, vol. 43 (2013), p. 1403.

[7] See Michael Mezher, "Lawmakers Urge HHS to Exercise 'March-In' Rights to Fight Higher Drug Costs," *States News Service*, January 11, 2016.

[8] Letter from Patricia Harsche Weeks, Immediate Past President, Association of University Technology Managers, to Dr. Mark Rohrbaugh, Director of the Office of Technology Transfer, NIH; http://www.autm.net/advocacy-topics/government-issues/advocacy-archives/march-in-rights/autm-response-to-march-in-provisions/.

This report reviews the availability of march-in rights under the Bayh-Dole Act. It begins by providing a brief overview of the patent system and innovation policy. The report then introduces the Bayh-Dole Act. The specific details of the march-in authority provided to federal agencies are reviewed next. The report then considers past efforts to obtain march-in authorization from NIH. The report closes with an identification of potential issues for congressional consideration.

The Patent System: An Overview

The Mechanics of the Patent System

The patent system is grounded in Article I, Section 8, Clause 8 of the U.S. Constitution, which states that "The Congress Shall Have Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.... " As mandated by the Patent Act of 1952,[10] U.S. patent rights do not arise automatically. Inventors must prepare and submit applications to the U.S. Patent and Trademark Office (USPTO) if they wish to obtain patent protection.[11] USPTO officials known as examiners then assess whether the application merits the award of a patent.[12] The patent acquisition process is commonly known as "prosecution."

In deciding whether to approve a patent application, a USPTO examiner will consider whether the submitted application fully discloses and distinctly claims the invention.[13] The examiner will also determine whether the invention itself fulfills certain substantive standards set by the patent statute. To be patentable, an invention must be useful, novel, and nonobvious. The requirement of usefulness, or utility, is satisfied if the invention is operable and provides a tangible benefit.[14] To be judged novel, the invention must not be fully anticipated by a prior patent, publication or other state-of-the-art knowledge that is collectively termed the "prior art."[15] A nonobvious invention must not have been readily within the ordinary skills of a competent artisan at the time the invention was made.[16]

If the USPTO allows the patent to issue, the patent proprietor obtains the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention.[17] Those who engage in these acts without the permission of the patentee during the term of the patent can be held liable for infringement. Adjudicated infringers may be enjoined from further infringing acts.[18] The patent statute also provides for the award of damages

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[9] Amy R. Schfield,"The Demise of Bayh-Dole Protections Against the Pharmaceutical Industry's Abuses of Government-Funded Inventions," *Journal of Law, Medicine & Ethics*, vol. 32 (2004), p. 780.

[10] P.L. 82-593, 66 Stat. 792 (codified at Title 35 United States Code).

[11] 35 U.S.C. §111.

[12] 35 U.S.C. §131.

[13] 35 U.S.C. §112.

[14] 35 U.S.C. §101.

[15] 35 U.S.C. §102.

[16] 35 U.S.C. §103.

[17] 35 U.S.C. §271(a).

[18] 35 U.S.C. §283.

"adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer."[19]

The maximum term of patent protection is ordinarily set at 20 years from the date the application is filed.[20] At the end of that period, others may employ that invention without regard to the expired patent.

Patent rights are not self-enforcing. Patentees who wish to compel others to observe their rights must commence enforcement proceedings, which most commonly consist of litigation in the federal courts. Although issued patents enjoy a presumption of validity, accused infringers may assert that a patent is invalid or unenforceable on a number of grounds.[21] The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) possesses national jurisdiction over most patent appeals from the district courts.[22] The U.S. Supreme Court enjoys discretionary authority to review cases decided by the Federal Circuit.[23]

Patents and Innovation Policy

The patent system is intended to promote innovation, which in turn leads to industry advancement and economic growth. The patent system in particular attempts to address "public goods problems" that may discourage individuals from innovating. Innovation commonly results in information that may be deemed a "public good," in that it is both non-rivalrous and non-excludable. Stated differently, consumption of a public good by one individual does not limit the amount of the good available for use by others; and no one can be prevented from using that good.[24]

The lack of excludability in particular is believed to result in an environment where too little innovation would occur. Absent a patent system, "free riders" could easily duplicate and exploit the inventions of others. Further, because they incurred no cost to develop and perfect the technology involved, copyists could undersell the original inventor. Aware that they would be unable to capitalize upon their inventions, individuals might be discouraged from innovating in the first instance. The patent system corrects this market failure problem by providing innovators with an exclusive interest in their inventions, thereby allowing them to capture their marketplace value.[25]

The patent system potentially serves other goals as well. The patent law may promote the disclosure of new products and processes, as each issued patent must include a description sufficient to enable skilled artisans to practice the patented invention.[26] In this manner the patent system ultimately contributes to the growth of information in the public domain. Issued patents may encourage others to "invent around" the patentee's proprietary interest. A patent proprietor may point the way to new products, markets, economies of production, and even entire industries. Others can build upon the disclosure of a patent instrument to produce their own technologies that fall outside the exclusive rights associated with the patent.[27]

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[19] 35 U.S.C. §284.

[20] 35 U.S.C. §154(a)(2). Although patent term is based upon the filing date, the patentee gains no enforceable legal rights until the USPTO allows the application to issue as a granted patent. A number of Patent Act provisions may modify the basic 20-year term, including examination delays at the USPTO and delays in obtaining marketing approval for the patented invention from other federal agencies.

[21] 35 U.S.C. §282.

[22] 28 U.S.C. §1295(a)(1).

[23] 28 U.S.C. §1254(1).

[24] See Deepa Varadarajan, "Of Fences and Definite Patent Boundaries," *Vanderbilt Journal of Entertainment and Technology Law*, vol. 18 (Spring 2016), p. 563.

[25] See Gregory N. Mandel, "Innovation Rewards: Solving the Twin Market Failures of Public Goods," *Vanderbilt Journal of Entertainment and Technology Law*, vol. 18 (Winter 2016), p. 303.

[26] 35 U.S.C. §112.

The patent system also has been identified as a facilitator of markets. If inventors lack patent rights, they may have scant tangible assets to sell or license. In addition, an inventor might otherwise be unable to police the conduct of a contracting party. Any technology or know-how that has been disclosed to a prospective licensee might be appropriated without compensation to the inventor. The availability of patent protection decreases the ability of contracting parties to engage in opportunistic behavior. By lowering such transaction costs, the patent system may make transactions concerning information goods more feasible.[28]

Patent protection may also encourage enterprises to commercialize and market existing inventions. Even though a new technology has already been patented, a firm might have to make refinements, construct manufacturing facilities, establish distribution channels, comply with government safety and regulatory requirements, and educate consumers prior to marketing. Second entrants to the market may not have to bear all of the first mover's costs. As a result, the exclusive rights provided by a patent may encourage not just the invention of new technologies, but also their commercialization.[29]

Through these mechanisms, the patent system may act in a more socially desirable way than its chief legal alternative, trade secret protection.[30] Trade secrecy guards against the improper appropriation of valuable, commercially useful, and secret information.[31] In contrast to patenting, trade secret protection does not result in the disclosure of publicly available information. That is because an enterprise must take reasonable measures to keep secret the information for which trade secret protection is sought. Taking the steps necessary to maintain secrecy, such as implementing physical security measures, also imposes costs that may ultimately be unproductive for society.

The patent system has long been subject to criticism, however. Some observers have asserted that the patent system is unnecessary due to market forces that already suffice to create an optimal level of innovation. The desire to obtain a lead time advantage over competitors may itself provide sufficient inducement to invent without the need for further incentives. Other commentators believe that the patent system encourages industry concentration and presents a barrier to entry in some markets. Additionally, while the patent incentive encourages the development of new medicines, some assert that it also contributes to the growing costs of healthcare.[32]

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[27] See Herbert Hovenkamp, "Antitrust and the Patent System: A Reexamination," *Ohio State Law Journal*, vol. 76 (2015), p. 467.

[28] Jonathan N. Barnett, "Cultivating the Genetic Commons: Imperfect Patent Protection and the Network Model of Innovation," *San Diego Law Review*, vol. 36 (2000), p. 1029-1030.

[29] Emily Michiko Morris, "The Many Faces of Bayh-Dole," *Duquesne Law Review*, vol. 54, p. 81.

[30] For further information on trade secrets, see CRS Report R43714, *Protection of Trade Secrets: Overview of Current Law and Legislation*, by Brian T. Yeh.

[31] See generally Michael R. McGurk and Jia W. Lu, "The Intersection of Patents and Trade Secrets," *Hastings Science & Technology Law Journal*, vol. 7 (Summer 2015), p. 189.

[32] See, e.g., Dan L. Burk and Mark A. Lemley, *The Patent Crisis and How the Courts Can Solve It* (2009); James Bessen and Michael Meuer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk* (2008); (continued...)

Each of these arguments for and against the patent system has some measure of intuitive appeal. However, they remain difficult to analyze on an empirical level. We lack rigorous analytical methods for studying the impact of the patent system upon the economy as a whole. As a result, current economic and policy tools do not allow us to calibrate the patent system precisely in order to produce an optimal level of investment in innovation at the lowest social costs.

The Bayh-Dole Act

Even prior to the Bayh-Dole Act, the federal government considered the intellectual property implications of R&D projects financed by public funds.[33] In 1963, the Kennedy Administration called for greater consistency in diverse agency practices regarding the disposition of rights to inventions made by government contractors. This early "Government Patent Policy" generally allowed the U.S. government to retain rights to inventions developed through government contracts.[34] However, the contractor could obtain title in specified circumstances. For example:

> [W]here the purpose of the contract is to build upon existing knowledge or technology to develop information, products, processes, or methods for use by the government, and the work called for by the contract is in a field of technology in which the contractor has acquired technical competence (demonstrated by factors such as know-how, experience, and patent position) directly related to an area in which the contractor has an established nongovernmental commercial position, the contractor shall normally acquire the principal or exclusive rights throughout the world in and to any resulting inventions, subject to the government acquiring at least an irrevocable non-exclusive royalty free license throughout the world for governmental purposes.[35]

In those situations, the 1963 policy retained significant government rights in privately held patents that resulted from publicly funded projects. In a prelude to today's march-in rights, the 1963 policy further provided:

> Where the principal or exclusive (except as against the government) rights to an invention are acquired by the contractor, the government shall have the right to require the granting of a license to an applicant royalty free or on terms that are reasonable in the circumstances to the extent that the invention is required for public use by governmental regulations or as may be necessary to fulfill health needs, or for other public purposes stipulated in the contract.[36]

The 1980 enactment of the Bayh-Dole Act altered the intellectual property landscape with respect to patents and government-sponsored R&D. Congress instead accepted the proposition that the lack of patent title discouraged private enterprise from advancing early-stage technologies into the marketplace. For example, suppose that a university researcher identifies a promising chemical compound using funds provided by the National Institutes of Health (NIH). Some observers believed that under pre-Bayh-Dole Act practices, a brand-name pharmaceutical company would be unlikely to undertake costly and risky clinical trials in order to convert that

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(...continued)

Adam B. Jaffe and Josh Lerner, *Innovation and Its Discontents: How Our Broken Patent System Is Endangering Innovation and Progress, and What To Do About It* (2004).

[33] Roberto Mazzoleni, "Patents and University-Industry Interactions in Pharmaceutical Research Before 1962: An Investigation of the Historical Justifications for Bayh-Dole," *Journal of High Technology Law*, vol. 10 (2010), p. 168.

[34] "Statement of Government Patent Policy," 28 *Federal Register* 10943, October 10, 1963.

[35] Ibid. at 10945.

[36] Ibid.

early-stage research into a drug approved by the Food and Drug Administration. Absent patent protection, generic firms could quickly introduce competing products. This view accepts that patents provide incentives not just for individuals to invent, but also to commercialize completed inventions.[37]

Under the Bayh-Dole Act, each nonprofit organization (including universities) or small business is permitted to elect within a reasonable time to retain title to any "subject invention" made under federally funded R&D.[38] The institution must commit to commercialization of the invention within a predetermined, agreed upon, timeframe. However, the government may keep title under "exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter." Additionally, the government may withhold title if the contractor "is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government"; in situations associated with national security; or when the work is related to the naval nuclear propulsion or weapons programs of the Department of Energy.[39]

Certain other rights are reserved for the government. The government retains "a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.... "[40] The government also retains "march-in rights" which enable the federal agency to require the contractor to license a third party to use the invention under certain circumstances.[41] This report discusses march-in rights at greater length below.

By its own terms, the Bayh-Dole Act applies only to nonprofit organizations (including universities) and small businesses. However, in a February 1983 memorandum concerning the vesting of title to inventions made under federal funding, then-President Ronald Reagan ordered all agencies to treat, as allowable by law, all contractors within the Bayh-Dole Act framework regardless of their size.[42] This longstanding practice lacks a legislative basis, however.

The Bayh-Dole Act authorizes the government to withhold public disclosure of information for a "reasonable time" until a patent application can be made.[43] Licensing by any contractor retaining title under this act is restricted to companies that will manufacture substantially within the United States. This requirement may be waived if domestic manufacture is not commercially feasible, or if the contractor or its successors made reasonable but ultimately unsuccessful efforts to license domestic manufacturers.[44] The Secretary of Commerce was provided the authority to issue regulations implementing the Bayh-Dole Act.[45]

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[37] See F. Scott Kieff, "Property Rights and Property Rules for Commercializing Inventions," *Minnesota Law Review*, vol. 85 (2001), p. 697.

[38] 35 U.S.C. §202(a).

[39] Ibid.

[40] 35 U.S.C. §202(c)(4).

[41] 35 U.S.C. §203.

[42] Memorandum on Government Patent Policy from President Ronald Reagan, to Heads of Executive Departments and Agencies, February 18, 1983, http://www.presidency.ucsb.edu/ws/index.php?pid=40945&st=&st1=.

[43] 35 U.S.C. §205.

[44] 35 U.S.C. §204.

[45] 35 U.S.C. §206. These regulations may be found at 37 C.F.R. Part 401.

March-In Rights

The Mechanics of March-In Rights

The Bayh-Dole Act provides the government with the ability to "march in" and grant licenses for patents that resulted from publicly funded R&D. In particular, march-in rights allow the federal government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants."[46] If the patent owner refuses to do so, the government may grant the license itself. The terms of the license must be "reasonable under the circumstances."

The Bayh-Dole Act specifies four circumstances under which march-in rights may be exercised. The federal agency that provided the funding arrangement under which the patented invention was made must reach one of the following determinations:

> (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
>
> (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
>
> (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
>
> (4) action is necessary because the agreement required by section 204 [generally requiring that patented products be manufactured substantially in the United States unless domestic manufacture is not commercially feasible] has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.[47]

With respect to the first of these conditions, the Bayh-Dole Act further defines the term "practical application" as "to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms."[48]

The Bayh-Dole Act states that any adversely affected "contractor, inventor, assignee, or exclusive licensee" may appeal a march-in rights petition to the United States Court of Federal Claims. The statute further explains that in cases described in paragraphs (1) and (3) above, march-in authority may not actually be exercised until all appeals or petitions are exhausted.[49]

The exercise of march-in rights does not invalidate or void the relevant patent. That patent remains extant and could presumably be enforced against entities that did not enjoy march-in rights. However, march-in rights grant a license—in other words, a permission—to the enterprise identified by the government. That entity may practice the patented invention without concern for infringement, so long as it satisfies the conditions stipulated in the march-in order, such as the payment of a royalty.

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[46] 35 U.S.C. §203(a).

[47] 35 U.S.C. §203(a).

[48] 35 U.S.C. §201(f).

[49] 35 U.S.C. §203(b).

March-in rights should be distinguished from the "nonexclusive, nontransferable, irrevocable, paid-up license" that the Bayh-Dole Act grants the U.S. government elsewhere.[50] This license solely benefits the federal government. Should another entity—such as a generic drug company or other enterprise—wish to practice the patented invention, then march-in rights provide a possible legal mechanism.

March-in rights are also distinct from the workings of another statute, 28 U.S.C. §1498(a).[51] That provision states:

> Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.

28 U.S.C. §1498(a) operates independently of the Bayh-Dole system. That statute applies to the use of a patented invention by the U.S. government, or one of its contractors with the authorization or consent of the U.S. government, without the permission of the patent proprietor. In such a case, the sole remedy for the patent owner is a suit in the U.S. Court of Federal Claims for monetary damages. An injunction is not available to the patent owner in such cases.

Three significant distinctions exist between march-in rights under the Bayh-Dole Act and 28 U.S.C. §1498(a). First, march-in rights apply only to patented inventions that were developed with the support of public funding. 28 U.S.C. §1498(a) applies to every U.S. patent, no matter what the sources of funding were. Second, private enterprises may take the initiative in requesting march-in rights from the government. 28 U.S.C. §1498(a) applies when the federal government practices the patented invention on its own behalf or requests a contractor to do so. Finally, recipients of march-in rights are awarded licenses "upon terms that are reasonable under the circumstances" and would presumably pay royalties to the patent proprietor. In contrast, under 28 U.S.C. §1498(a) the patent proprietor commences litigation and may be awarded damages to compensate for the use of the government or its contractors.

March-In Petitions

March-in rights have never been exercised during the 35-year history of the Bayh-Dole Act. Apparently the only federal agency that has even received a petition is the National Institutes of Health (NIH).[52] In particular, six petitions have been filed requesting that the NIH "march in" with respect to a particular pharmaceutical. Each petition was denied. A common theme of each of the denials was the agency's views that concerns over drug pricing were not, by themselves, sufficient to provoke march-in rights. The six requests were:

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[50] 35 U.S.C. §202(c)(4).

[51] See Justin Torres, "The Government Giveth, and the Government Taketh Away: Patents, Takings, and 28 U.S.C. § 1498," *New York University Annual Survey of American Law*, vol. 63 (2007), p. 315; Bradley M. Taub, "Why Bother Calling Patents Property? The Government's Path to License Any Patent and Maybe Pay For It," *John Marshall Review of Intellectual Property Law*, vol. 6, p. 151.

[52] The author of this report has not located any record of any march-in petition filed at any other federal agency that funds R&D. See U.S. Government Accountability Office, *Federal Research: Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions*, GAO-09-742, July 2009, http://www.gao.gov/assets/300/293020.pdf (noting that the Department of Defense, Department of Energy, and National Aeronautics and Space Administration "have neither discovered nor received information that would lead them to initiate a march-in proceeding or exercise their march-in authority during the last 20 years.").

> ***CellPro, Inc.*** (1997). CellPro requested that the government exercise march-in rights after being found to infringe patents held by the contractor. Although the NIH recognized that CellPro's device was the only FDA-approved product on the market, the agency observed that (1) the contractor and its licensees had not sought immediately to enjoin CellPro and (2) that they were making reasonable efforts to commercialize their own product. As a result, the agency declined to initiate march-in procedures.[53]
>
> ***Norvir/ritonavir*** (2004). The petitioners, which included some Members of Congress, asked the NIH to exercise march-in rights due to perceived concerns over the high price of this HIV/AIDS treatment. The agency declined to initiate march-in proceedings because it deemed Abbott Laboratories, Inc., to have made the drug available to the public on a sufficient basis.[54]
>
> ***Xalatan/latanoprost*** (2004). Petitioners asserted that the price of this glaucoma treatment was higher than that of other nations. The NIH declined to initiate march-in proceedings because the drug was readily available for use by the public.[55]
>
> ***Fabrazyme/agalsidase beta*** (2010). This petition asked the NIH to grant an open license on certain patents relating to this treatment for Fabry disease. According to the petitioners, Genzyme Corporation was encountering difficulties in manufacturing sufficient quantities of the drug. The NIH did not initiate a march-in proceeding because (1) Genzyme was working diligently to resolve its manufacturing difficulties and (2) other enterprises were unlikely to obtain FDA marketing approval on agalsidase beta products before those problems were addressed.[56]
>
> ***Norvir/ritonavir*** (2012). The second petition against this HIV/AIDS drug more specifically requested the NIH to invoke march-in rights when prices in the United States were greater than other high-income nations. The NIH did not initiate march-in right proceedings because, in the view of the agency, such pricing disparities did not trigger any of the four statutory criteria for marching in.[57]
>
> ***Xtandi/enzalutamide*** (2016). The petitioner asserted both that the prostate cancer drug Xtandi had an average wholesale price of $129,269 per year; and that this price was much higher than in other high-income nations. The NIH declined to

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[53] Harold Varmus, Director, NIH, *Determination in the Case of Petition of CellPro,Inc.*, August 1, 1997, http://web.archive.org/web/20070102183356/http:/www.nih.gov/icd/od/foia/cellpro/pdfs/foia_cellpro39.pdf.

[54] Elias A. Zerhouni, Director, NIH, *In the Case of Norvir Manufactured by Abbott Laboratories, Inc.*, July 29, 2004, http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf.

[55] Elias A. Zerhouni, Director, NIH, *In the case of Xalatan, Manufactured by Pfizer, Inc.*, September 17, 2004, https://www.ott.nih.gov/sites/default/files/documents/policy/March-in-xalatan.pdf.

[56] Francis S. Collins, Director, NIH, *Determination in the Case of Fabrazyme Manufactured by Genzyme Corporation*, December 1, 2010, https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf.

[57] Francis S. Collins, Director, NIH, *Determination in the Case of Norvir Manufactured by AbbVie*, November 1, 2013, https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf.

> initiate a march-in investigation because sales of the product were increasing and no evidence suggested that the product was in short supply.[58]

The NIH has offered some observations about the role of march-in rights during these proceedings. In its response to the 1997 CellPro petition, the agency stated its reluctance to undermine the exclusivities offered by the patent system:

> We are wary, however, of forced attempts to influence the marketplace for the benefit of a single company, particularly when such actions may have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies. The patent system, with its resultant predictability for investment and commercial development, is the means chosen by Congress for ensuring the development and dissemination of new and useful technologies. It has proven to be an effective means for the development of health care technologies. In exercising its authorities under the Bayh-Dole Act, NIH is mindful of the broader public health implications of a march-in proceeding, including the potential loss of new health care products yet to be developed from federally funded research.[59]

In the 2004 proceedings regarding Norvir/ritonavir, the agency spoke more specifically about drug pricing:

> Finally, the issue of the cost or pricing of drugs that include inventive technologies made using Federal funds is one which has attracted the attention of Congress in several contexts that are much broader than the one at hand. In addition, because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by NIH, the NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively.[60]

The NIH has also observed that another statute, the Drug Price Competition and Patent Term Restoration Act, P.L. 98-417, plays a role in the public availability of medicines.[61] Better known as the Hatch-Waxman Act, this legislation allows generic drug companies to develop their own products without incurring liability for patent infringement. It also allows generic drug companies to market their products prior to the expiration of relevant patents, although if they do so they may incur infringement liability at that time.[62]

Debate over March-In Rights

Concerns over the lack of assertion of march-in rights have been expressed for the past two decades. In 2001, Peter S. Arno[63] and Michael H. Davis[64] published an article in the *Tulane Law*

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[58] Letter from Francis C. Collins, Director, NIH, to Andrew S. Goldman, Knowledge Ecology International, June 20, 2016, http://keionline.org/sites/default/files/Final-Response-Goldman-6.20.2016.pdf.

[59] Harold Varmus, Director, NIH, *Determination in the Case of Petition of CellPro,Inc.*, August 1, 1997, http://web.archive.org/web/20070102183356/http:/www.nih.gov/icd/od/foia/cellpro/pdfs/foia_cellpro39.pdf.

[60] Elias A. Zerhouni, Director, NIH, *In the Case of Norvir Manufactured by Abbott Laboratories, Inc.*, July 29, 2004, http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf.

[61] Francis S. Collins, Director, NIH, *Determination in the Case of Fabrazyme Manufactured by Genzyme Corporation*, December 1, 2010, https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf, p. 9.

[62] CRS Report R41114, *The Hatch-Waxman Act: Over a Quarter Century Later*, by Wendy H. Schacht and John R. Thomas, The Hatch-Waxman Act: Over a Quarter Century Later.

[63] Dr. Arno was then a Professor of the Albert Eistein College of Medicine/Montefiore Medical Center.

[64] Mr. Davis was then a Professor of the Cleveland State College of Law.

Review asserting that the Bayh-Dole Act "has had a powerful price-control clause since its enactment in 1980 that mandates that inventions resulting from federally funded research must be sold at reasonable prices."[65] According to Arno and Davis, "the solution to high drug prices does not involve new legislation but already exists in the unused, unenforced march-in provision of the Bayh-Dole Act."[66] Arno and Davis followed this article with a 2002 editorial published in the *Washington Post*, stating in part:

> Although Bayh-Dole has been in place for 20 years, the government has never enforced it—not even once. That, despite the AIDS crisis at home and abroad, despite the millions of elderly and chronically ill Americans in need of affordable prescription drugs and the 40 million others who have no health insurance coverage whatever—and despite the general hand-wringing over the skyrocketing costs of pharmaceuticals.[67]

Former Senators Birch Bayh and Robert Dole, as they were then, responded with an editorial published in the *Washington Post* less than a month later. The editorial states in part:

> Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government.... The [Arno and Davis] article also mischaracterizes the rights retained by the government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of the resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.[68]

Dialogue over the use of march-in rights was renewed in 2016, resulting in several exchanges between some Members of Congress, on one hand, and the Department of Health and Human Services (HHS) on the other. In an undated letter that was reportedly sent on January 11, 2016, the Honorable Lloyd Doggett, joined by 51 Members of Congress, addressed a letter to Secretary Sylvia Matthews Burwell of HHS and NIH Director Francis S. Collins. The letter in part requested NIH to provide official guidance regarding the situations in which march-in rights should apply.[69]

Secretary Burwell responded by letter on March 2, 2016. Her letter states in part that the Bayh-Dole Act's march-in right was "strictly limited and can only be exercised if the agency conducts an investigation and determines that specific criteria are met, such as alleviating health or safety needs or when effective steps are not being taken to achieve practical application of the inventions." She also concluded that "the statutory criteria are sufficiently clear and additional guidance is not needed."[70]

Representative Lloyd Doggett sent an additional letter to Secretary Burwell and Director Collins on March 28, 2016. Signed by eleven other Members of Congress, the letter encourages the NIH to conduct a public hearing regarding the request of public interest groups to invoke march-in rights to the cancer drug Xtandi/enzalutamide. The letter explains:

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[65] Peter S. Arno and Michael H. Davis, "Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part from Federally Funded Research," 75 *Tulane Law Review* (2001), p. 631.

[66] Ibid.

[67] Peter Arno and Michael Davis, "Paying Twice For the Same Drugs," *Washington Post,* March 27, 2002, at A21.

[68] See Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," *Washington Post*, April 11, 2002, at A28.

[69] Michael Mezher, "Lawmakers Urge HHS to Exercise 'March-In' Rights to Fight Higher Drug Costs," *States News Service*, January 11, 2016.

[70] Letter from Sylvia M. Burwell, Secrtary of Health and Human Services, to The Honorable Lloyd Doggett, U.S. House of Representatives, March 2, 2016, http://freepdfhosting.com/be7532cfc0.pdf.

> NIH was recently petitioned to exercise these march-in rights on Xtandi, a prostate cancer drug developed at the University of California, Los Angeles (UCLA) through taxpayer supported research grants from the U.S. Army and NIH grants. The petition states that a Japanese licensee, Astellas, is charging Americans $129,000 for this drug, which sells in Japan and Sweden for $39,000, and in Canada for $30,000. We do not think that charging U.S. residents more than anyone else in the world meets the obligation to make the invention available to U.S. residents on reasonable terms.[71]

As noted above, the NIH denied march-rights for Xtandi/enzalutamide on June 20, 2016.[72]

Congressional Issues and Options

To date, no bills have been introduced in the 114th Congress to address march-in rights under the Bayh-Dole Act. Therefore, if Congress deems the current situation to be acceptable, then no action need be taken. Other options include clarifications that further stipulate the circumstances under which march-in rights may be invoked, either by statutory amendment or the encouragement of regulatory refinements. Congress could, for example, define with greater clarity the precise circumstances under which a patented invention is deemed "available to the public on reasonable terms."[73] Congress could also define with greater specificity when march-in rights are needed to "alleviate health or safety needs,"[74] particularly with respect to inventions that might be perceived as too costly for many consumers to afford.

Other options include transfer of oversight of administering march-in rights. Currently the Bayh-Dole Act assigns the agency that provided funds that led to the patented invention responsibility for exercising these rights.[75] Another entity might have distinct perspectives than the funding agency and might reach different conclusions on whether to exercise march-in rights.

Transferring decisionmaking authority to a distinct entity might also eliminate any perceived conflicts of interest with respect to march-in rights. Former employees of federal agencies often wish to pursue careers within the private sector and may wish to maintain good relationships with those enterprises. In addition, agency officials may themselves be named inventors on patents to which march-in rights apply.[76] These factors could conceivably lead to a perception of bias against the institution of march-in rights.

Some commentators have also suggested that Congress should establish a centralized database of inventions subject to the Bayh-Dole Act.[77] Such a record would potentially improve the ability of the public to track its R&D investments and observe the degree to which these investments have resulted in new products for the marketplace. If a further level of monitoring were desirable, one possibility would be to require licensees of patents subject to the Bayh-Dole Act to submit periodic reports disclosing both their efforts at introducing the patented inventions to the public and their pricing policies.

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[71] Letter from Lloyd Doggett, House of Representatives, to The Honorable Sylvia Burwell, Secretary, Department of Health and Human Services, March 28, 2016, http://freepdfhosting.com/1c677ecdfc.pdf.

[72] "Feds Won't Lower Price of Prostate-Cancer Drug," *Seattle Times*, June 21, 2016.

[73] 35 U.S.C. §201(f).

[74] 35 U.S.C. §203(a)(2).

[75] 35 U.S.C. §203(a).

[76] The petition for rehearing of the Fabrazyme march-in decision asserted that NIH Director Francis Collins was named as an inventor on nineteen patents potentially subject to march-in rights. Letter from C. Allen Black, Jr., Attorney at Law, to Mark Rohrbaugh, Office of Technology Transfer, NIH, April 5, 2011, http://patentdocs.typepad.com/files/nih-petition-for-rulemaking-and-rehearing-90.pdf.

[77] Ryan Whalen, "The Bayh-Dole Act & Public Rights in Federally Funded Inventions: Will the Agencies Ever Go Marching In?," *Northwestern University Law Review*, vol. 109 (2015), pp. 1111-12.

Other commentators also have urged reconsideration of the statutory requirement that in certain cases all judicial appeals be exhausted before march-in authority may actually be exercised.[78] Under current law, even though a federal agency has authorized march-in rights, they may at times not be used until the patent proprietor has taken his case as far as the Supreme Court of the United States. As Arti K. Rai[79] and Rebecca S. Eisenberg[80] assert, "the tolerance for protracted delays inherent in the current process is at odds with the time-sensitive nature of the interests reflected in the substantive standard, such as achieving practical application of the invention 'within a reasonable time' and 'alleviat[ing] health or safety needs.'"[81] This possibility of delay could also possibly discourage march-in petitions in the first instance.

Still other commentators have suggested that Congress should take further steps to ensure that the best candidate receives licenses for patents subject to the Bayh-Dole Act. Under current law, government contractors may choose to license their inventions to anyone. Such a system may not place these inventions in the most capable hands, either from the perspective of the contractor or of the public.[82] Another option might be an open-bidding auction that might better ensure that patents on inventions developed through government funding are licensed to the most capable enterprise.[83]

Concluding Observations

Current dialogue over march-in rights involves a familiar policy debate in intellectual property law. On the one hand, the patent laws are intended to promote the labors that lead to innovation. Critics of the use of march-in rights believe that diluting the patent incentive will discourage private investment and ultimately work against the aims of the Bayh-Dole Act. But others say that the patent laws are also intended to distribute the fruits of those labors to the public. This goal is most visibly achieved when patents expire and previously proprietary technologies enter the public domain. However, some observers believe that march-in rights provide an unused mechanism for discouraging excessive profiteering and providing the public an appropriate return on its R&D investments during a patent's term. Striking a balance between these competing views regarding the commercialization of federally funded research remains a matter of congressional judgment.

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[78] 35 U.S.C. §203(b).

[79] Arti K. Rai is the Elvin R. Latty Professor of Law at the Duke University School of Law.

[80] Rebecca S. Eisenberg is the Robert and Barbara Luciano Professor of Law at the University of Michigan Law School.

[81] Arti K. Rai and Rebecca S. Eisenberg, "Bayh-Dole Reform and the Process of Biomedicine," *Journal of Law and Contemporary Problems*, vol. 66 (2003), p. 311.

[82] Peter Lee, "Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer," *California Law Review*, vol. 100 (2012), p. 1521.

[83] See Whalen, *supra*.

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Sent: 11/22/2017 5:27:51 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Wertz, Jennifer (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e6cb9797cef40f1b40e777afe3795d7-wertzj]; Plude, Denise (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91f83d681d984eaa8fe3de287aebfa01-pludede]; Fennington, Kelly (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e2d306aa244429b0f51d365bd24a26-fenningk]; Ampey, Bryan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9672b522d0b34f3792e2934dac636a57-ampeybc]
Subject: RE: WF 368759 - due 11/27

I understand that, but it feels like we should be conveying the information in similar ways. Also, b5 b5 b5 It seems like information from the previous letter could be added (see red, but it doesn't insert seamlessly into flow):

Dear Mr. Goldman:

b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, November 22, 2017 12:17 PM
To: Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>
Cc: Wertz, Jennifer (NIH/OD) [E] <wertzj@od.nih.gov>; Plude, Denise (NIH/OD) [E] <pludede@mail.nih.gov>; Fennington,

Kelly (NIH/OD) [E] <fenningk@od.nih.gov>; Ampey, Bryan (NIH/OD) [E] <bryan.ampey@nih.gov>
Subject: Re: WF 368759 - due 11/27

They are a bit different, one to KEI who accused Penn of non-compliance and this one to U Penn who had explained to KEI and NIH that they are in compliance. KEI agreed.

Sent from my iPhone

On Nov 22, 2017, at 12:05 PM, Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov> wrote:

> Shouldn't this one have the same information in it (i.e., be as closely parallel) as the one that just went out?
>
> See attached.
>
> **From:** Plude, Denise (NIH/OD) [E]
> **Sent:** Wednesday, November 22, 2017 7:34 AM
> **To:** Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Fennington, Kelly (NIH/OD) [E] <fenningk@od.nih.gov>; Ampey, Bryan (NIH/OD) [E] <bryan.ampey@nih.gov>
> **Cc:** Wertz, Jennifer (NIH/OD) [E] <wertzj@od.nih.gov>
> **Subject:** RE: WF 368759 - due 11/27
> **Importance:** High
>
> Approve?
>
> **From:** Rohrbaugh, Mark (NIH/OD) [E]
> **Sent:** Tuesday, November 21, 2017 4:09 PM
> **To:** Plude, Denise (NIH/OD) [E] <pludede@mail.nih.gov>
> **Subject:** RE: WF 368759 - due 11/27
>
> Clear with no comments
>
> **From:** Plude, Denise (NIH/OD) [E]
> **Sent:** Tuesday, November 21, 2017 3:55 PM
> **To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
> **Subject:** WF 368759 - due 11/27
> **Importance:** High
>
> **Work Folder Information**
> **Work Folder:** WF 368759
> **Process:** Clearance
> **Program Analyst:** Whitfield, Michelle D. (NIH/OD) [E]
> **Due Date:** November 27, 2017
> **WF Subject:** OS Direct Reply- Request to Investigate University of Pennsylvania failure to disclose federal funding of CAR T patents.
> **IC:** od_osp
> **From:** Love, JamesSinghroy, DianeGoldman, Andrew S.
> **To:** Hargan, Eric D.
> **Remarks:** Assigned to OGC, NCI, OLPA, OCPL, and OSP for clearance by Nov. 27. Draft prepared by OER. Please provide your clearance and/or comments (regarding document named

"Rnd1 DRAFT RESPONSE to KEI 11202017ah_pj" in the draft response folder) to ES by c.o.b. Nov. 27. Thank you.

<Rnd1 DRAFT Response to UPENN 11212017ah.docx>

<2 Email 00388983 16 11 2017.pdf>

<1 Letter.Hon.Hargan.10.18.17.pdf>

From: Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]
Sent: 8/13/2018 6:35:47 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: FYI

Still has not been assigned to me. I have alerted OER of the following but assignment...yet.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Friday, August 10, 2018 5:09 PM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: FYI

Work Folder Information
Work Folder: WF 375121
Process: FYI
Program Analyst: Whitfield, Michelle D. (NIH/OD) [E]
Due Date:
WF Subject: KEI would like HHS to investigate the failure to disclose NIH funding in patents on Vizamyl (University of Pittsburgh).
IC: od_osp
From: Cassedy, Claire
To: NLN, NFNHammersla, AnnLevinson, DanielCollins, FrancisAzar, Alex
Remarks: FYI for OSP and OGC. Assigned to OER for necessary action to b5
b5

From: Lambert, Richard (NIH/NIAID) [C] [/O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=LAMBERTR]
Sent: 6/21/2017 11:57:16 AM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: FW: [Ip-health] The Nation: The Government Created This Zika Vaccine. Why Should Big Pharma Reap the Profits?

fyi

Richard A. Lambert
Contractor
National Institute of Allergy and Infectious Diseases
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-----Original Message-----
From: Andrew S. Goldman [mailto:andrew.goldman@keionline.org]
Sent: Tuesday, June 20, 2017 2:13 PM
To: IP-health <Ip-health@lists.keionline.org>
Subject: [Ip-health] The Nation: The Government Created This Zika Vaccine. Why Should Big Pharma Reap the Profits?

https://www.thenation.com/article/the-government-created-this-zika-vaccine-why-should-big-pharma-reap-the-profits/

The Government Created This Zika Vaccine. Why Should Big Pharma Reap the Profits?

Lawmakers are concerned that giving a drug company a monopoly on the promising vaccine could make it unaffordable.

By Richard Eskow

TODAY 10:59 AM

It's a familiar, if tragic, pattern: A medical breakthrough is discovered at public expense, only to be licensed to a private corporation that earns billions of dollars by making it unaffordable for ordinary people.

The latest such giveaway involves a vaccine for the Zika virus, which can cause microcephaly, blindness, deafness, and calcification of the brain in children whose mothers were infected during pregnancy. Though the new vaccine is still being tested, it shows great promise. It was developed at the Walter Reed Army Institute for Research, and the Department of the Army funded its development.

Now, the Army is planning to grant exclusive rights to this potentially groundbreaking medicine–along with as much as $173 million in funding from the Department of Health and Human Services–to the French pharmaceutical corporation Sanofi Pasteur. Sanofi manufactures a number of vaccines, but it's also faced repeated allegations of overcharges and fraud. Should the vaccine prove effective, Sanofi would be free to charge whatever it wants for it in the United States. Ultimately, the vaccine could end up being unaffordable for those most vulnerable to Zika, and for cash-strapped states.

<snip>
--
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From: Roering, Jill (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BEF9E009E2C945968B0E1099E33D65BB-ROERINGJ]
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CC: Hammersla, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87fb28aa23744c0b855ef0683ac2e8b4-hammerslaa]; Rogers, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b23ef4ca2fa14a6eb174ee611953a396-rogersk]
Subject: FW: ES - WF 371408 - Response Creation (CC) (KEI and Penn)
Attachments: WF371408 Penn Unversity - Documents.pdf; WF371408 - Documents.pdf

Good Afternoon Dale and Mark,

We've received the following action item; "Please craft a response to Robert Firestone on behalf of Dr. Collins. Forward draft to Exec. Sec. for OD clearance before mailing. DUE: 04/05/18 COB. Also forwarded as FYI to OMA, OM, OER, OIR, and OGC."

Given that this is a KEI-related matter, **b5**

Any guidance on this matter would be greatly appreciated.

Kind regards,

Jill

JILL ROERING
Acting Deputy Director, Office of Technology Transfer
Sr. Patent Management Analyst

National Institutes of Health
Office of Intramural Research
Office of Technology Transfer

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This email may contain confidential and/or privileged information intended only for the addressee. If you have received this communication in error, please notify the sender via email that you have received the communication in error, and permanently delete the message. Thank you.

From: White, Tracy (NIH/OD) [E]
Sent: Thursday, March 29, 2018 11:36 AM
To: Roering, Jill (NIH/OD) [E] <roeringj@od.nih.gov>; Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>
Subject: FW: ES - WF 371408 - Response Creation (CC)

Hi, Jill

This WF is ready for to review.

From: EDRMS_NO_REPLY@mail.nih.gov [mailto:EDRMS_NO_REPLY@mail.nih.gov]
Sent: Thursday, March 29, 2018 11:18 AM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>; White, Tracy (NIH/OD) [E] <whitever@od.nih.gov>; White, Tracy (NIH/OD) [E] <whitever@od.nih.gov>
Subject: ES - WF 371408 - Response Creation (CC)

To whom it may concern:

Message from the Director's Document and Records Management System (DDRMS)

You have received a task notification requiring your attention.

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Work Folder Information
Work Folder: WF 371408
Process: Response Creation
Program Analyst: Crone, Colleen (NIH/OD) [E]
Due Date: April 05, 2018
WF Subject: Robert Firestone (General Counsel, Univ. of PA) writes to Dr. Collins in response to KEI letter regarding Rader research and patents issued to the Univ. of PA.
IC: od_ott
From: Firestone, Robert
To: Collins, FrancisGoldstein, BruceRoering, JillRogers, Karen
Remarks: Assigned to OTT for direct reply with clearance. Please craft a response to Robert Firestone on behalf of Dr. Collins. Forward draft to Exec. Sec. for OD clearance before mailing. DUE: 04/05/18 COB. Also forwarded as FYI to OMA, OM, OER, OIR, and OGC.

Additional instructions are included on the task form, click the link to open the Task

Penn
University of Pennsylvania

PENN
Medicine

Robert F. Firestone, Esq.
Associate General Counsel
Direct Dial: 215.746.5266
Robert.firestone@ogc.upenn.edu

Via Email to Francis.Collins@nih.gov and First Class Mail
March 28, 2018

Honorable Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
Office of the Director
BG 1 Room 118A, 1 Center Drive
Bethesda, MD 20814

RE: Knowledge Ecology International (KEI) March 19, 2018 submission to NIH, regarding four M01 awards to the University of Pennsylvania, and six patents issued to the University of Pennsylvania

Dear Dr. Collins:

I represent The Trustees of the University of Pennsylvania and one of its faculty members, Dr. Daniel Rader, and am responding to KEI's March 19, 2018 submission to the NIH Office of Technology Transfer. KEI cites four M01 awards (see Table 3 in KEI's March 19, 2018 submission), and alleges that the University inappropriately failed to disclose these M01 awards when applying for patents on a dosing method for which the University has obtained six U.S. patents. KEI relies upon inaccurate facts and makes certain incorrect assumptions. As set forth below, the dosing method inventions were conceived and reduced to practice as part of a Phase I/II study funded by the Doris Duke Charitable Foundation, not the federal government. They were not "subject inventions" conceived or first reduced to practice in the performance of a specific research project funded by NIH. Therefore, the University was not required to notify NIH when the inventions were made, or disclose an M01 award in its patent application.

In 2002, Dr. Rader wrote a funding proposal to the Doris Duke Charitable Foundation to conduct a specific research project: a Phase I/II study of the safety and efficacy of pharmacologic inhibition of a microsomal transfer protein (MTP) in patients with homozygous familial hypercholesterolemia (HoFH). The foundation decided to fund this discrete clinical trial, as well as other research projects Dr. Rader proposed, for five years. Study subjects received treatments, and data were collected, from approximately June, 2003 through February, 2004. Dr. Rader's protocol was designed to test a particular dosing strategy for BMS-201038, an MTP inhibitor. Bristol Myers Squibb previously had decided not to commercially develop BMS-201038, because in earlier studies, subjects experienced diarrhea and negative liver enzyme elevations. But Dr. Rader had an idea for a different dosing methodology as a way to minimize these negative side effects, and wanted to study whether changes in the dosing could be safe and effective in patients with HoFH.

M01 awards were infrastructure awards to support a General Clinical Research Center (GCRC) at the Hospital of the University of Pennsylvania, not an award to a specific scientist to conduct a discrete, specified research project (like an R01 award, as one example.) A GCRC was a discrete unit

Office of the General Counsel
2929 Walnut Street, Suite 400 Philadelphia, PA 19104-5099
Main Telephone Number: 215-746-5200

of research beds within an academic medical center or hospital, separated from general care wards, that the government funded and wanted to be a shared infrastructure resource available to many different scientists, as a way to reduce overall costs for each separate, discrete research project. (For example, it would make no sense for each researcher at Penn to obtain funding for and hire separate nurses, or buy separate blood pressure machines, when these equipment and staff could be shared across projects more efficiently.) M01 awards were used for physical facility renovations to build and maintain the discrete unit within a hospital, and to pay operational expenses such as nurse and other staff salaries, shared equipment, and operating supplies. See NIH's Activity Code definition for M01 awards at: https://grants.nih.gov/grants/funding/ac_search_results.htm?Activity_Code=M01&Search_Type=Indiv

As part of Dr. Rader's Phase I/II study, study subjects received services at Penn's GCRC during June, 2003 to Feb. 2004, such as having their blood pressure, heart rate, and temperature checked, weight measured, and other nursing and dietician services. (Therefore, KEI is wrong to cite three M01 awards to Penn for the periods December, 2000 through November, 2001; from December, 2001 through November, 2002; and from December, 2004 through November, 2005. The dosing methodology claimed in the patent application was not conceived or first reduced to practice during these periods, so the M01 awards to Penn for its GCRC outside of June, 2003 to Feb. 2004 are irrelevant.)

Under Bayh-Dole, the dosing methodology claimed in Penn's patent application, was not a "subject invention" conceived or first reduced to practice in the performance of the M01 award. The dosing methodology was conceived and first reduced to practice in the performance of the Phase I/II clinical trial funded solely by the Doris Duke Charitable Foundation. Therefore, the University of Pennsylvania did not, and was not required to, disclose the dosing methodology invention to NIH as a "subject invention," and the University of Pennsylvania was not required to, and did not, disclose federal funding of its GCRC when Penn filed its patent application.

If NIH has any questions or would like additional information from the University, please contact me directly.

Sincerely,

Robert F. Firestone

Robert F. Firestone
Associate General Counsel
The Trustees of the University of Pennsylvania

courtesy copies to:
Karen Rogers, Acting Director, Office of Technology Transfer, NIH (rogersk@mail.nih.gov)
Jill Roering, Acting Deputy Director, Office of Technology Transfer, NIH (roeringj@mail.nih.gov)
Bruce Goldstein, Assistant Director, Monitoring & Enforcement, Office of Technology Transfer, NIH (goldsteb@mail.nih.gov)
Andrew S. Goldman, Counsel, Policy and Legal Affairs, KEI (andrew.goldman@keionline.org)
James Love, Director, KEI (james.love@keionline.org)
Dr. Daniel Rader, University of Pennsylvania

From: Firestone, Robert
Sent: Wed, 28 Mar 2018 20:55:15 +0000
To: Collins, Francis (NIH/OD) [E];Rogers, Karen (NIH/OD) [E];Roering, Jill (NIH/OD) [E];Goldstein, Bruce (NIH/OD) [E]
Subject: Penn Response to KEI Letter to NIH dated March 19, 2018
Attachments: 2018-03-28 Penn Response to NIH re KEI Allegations-Rader-Executed.pdf

Dr. Collins, Ms. Rogers, Ms. Roering, and Mr. Goldstein: I have attached a letter from the University of Pennsylvania and Dr. Daniel Rader in response to the March 19, 2018 letter NIH received from Knowledge Ecology International, regarding research led by Dr. Rader and patents issued to the University of Pennsylvania. Thank you, Bob Firestone

Robert F. Firestone, Esq.
Associate General Counsel
University of Pennsylvania and Penn Medicine
2929 Walnut Street, Suite 400
Philadelphia, PA 19104-5099
Phone: 215-746-5266
Assistant: b6
Robert.Firestone@ogc.upenn.edu

From:	Burke, Andy (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=305E280EDC664E68939D4348603F56E6-BURKEAR]
Sent:	6/24/2019 8:21:10 PM
To:	Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject:	FW: Inquiry regarding 84 FR 28063 Doc 2019-12707 - Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer

Hi Mark,

b5

Thanks,

Andy

From: Claire Cassedy <claire.cassedy@keionline.org>
Sent: Monday, June 24, 2019 4:17 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Subject: Re: Inquiry regarding 84 FR 28063 Doc 2019-12707 - Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer

Dear Mr. Burke,

Thank you very much for your prompt reply. I have one more question regarding this proposed license:

-In working towards executing this license, has the NIH sought advice from the Attorney General (as is required under 40 USC § 559) to determine if the "disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law"?

I appreciate all your assistance on these inquiries.

Best Regards,
Claire Cassedy

--
Claire Cassedy
Knowledge Ecology International
1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
Tel.: 1.202.332.2670

On Mon, Jun 24, 2019 at 3:42 PM Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

> Dear Claire,
>
> Thank you for your email. Answers to your questions are embedded below.

Regards,

Andy

Andrew R. Burke, Ph.D.

Senior Technology Transfer Manager

National Cancer Institute

9609 Medical Center Drive, Rm 1E550

Rockville, MD 20850

Direct: (240) 276-5484

Email: andy.burke@nih.gov

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From: Claire Cassedy <claire.cassedy@keionline.org>
Sent: Monday, June 24, 2019 12:33 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Subject: Inquiry regarding 84 FR 28063 Doc 2019-12707 - Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer

Dear Mr. Burke,

I am writing in reference to the Federal Register notice (84 FR 28063 Doc 2019-12707) regarding, "Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer," for which you are listed as the contact for inquiries. I was hoping you could provide me with some further information regarding the status of the technologies.

1. At what stage of development are the inventions listed?

Answer: With respect to the advertised fields of use, the technologies are at a "pre-clinical" stage of development.

2. Has the government funded any clinical trials relevant to these technologies?

Answer: I am not aware of any US government-funded clinical trials utilizing the referenced technologies within the advertised fields of use.

3. If the government has provided funding, how much has been spent by the government on these trials? Can you provide NCT numbers?

Answer: NA

4. How many years of exclusivity have been offered in this agreement, and what will the royalty rate be?

Answer: These terms will be the subject of negotiation and are not known at this time.

5. Regarding the company to receive the licenses, Tailored Therapeutics, LLC are any former NIH employees associated with the company?

Answer: Questions regarding employees or associates of the company should be directed to the company.

Thank you in advance for your assistance in this matter.

Best Regards,
Claire Cassedy

--

Claire Cassedy

Knowledge Ecology International

1621 Connecticut Avenue NW

Suite 500

Washington, DC 20009

Tel.: 1.202.332.2670

From: Ferguson, Steve (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AEC79B088CE947819EADD4BF420AA54B-FERGUSOS]
Sent: 5/25/2018 2:21:06 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Lambert, Richard (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9668e9326d084ac893665b084fdfd4fe-lambertr]
Subject: FW: Patent Docs

FYI, in case you didn't see this case write-up. I was wondering if b5 b5

Regards,

Steven M. Ferguson, CLP
Special Advisor
NIH Office of Technology Transfer
6011 Executive Boulevard, Suite 325
Rockville, MD 20852
Phone: (301) 435-5561
Email: sf8h@nih.gov
Web: www.ott.nih.gov

From: noreply+feedproxy@google.com [mailto:noreply+feedproxy@google.com]
Sent: Friday, May 25, 2018 7:11 AM
To: Ferguson, Steve (NIH/OD) [E] <fergusos@od6100m1.od.nih.gov>
Subject: Patent Docs

Patent Docs

AIDS Healthcare Foundation, Inc. v. Gilead Sciences, Inc. (Fed. Cir. 2018)

Posted: 24 May 2018 08:53 PM PDT

By Kevin E. Noonan -- Ever since the Supreme Court loosened the reins on declaratory judgment actions in patent cases twelve years ago, in MedImmune v. Genentech, courts have decided cases fleshing out the metes and bounds of the factual predicates thereof. One of the most persistent questions is what is the extent to which a declaratory judgment plaintiff can base the action not on traditional grounds (such as those between competitors for a patented product) but rather on the effects of patents on consumers or beneficiaries of a patented compound; these questions have arisen with greatest vigor over patented....

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From: Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]
Sent: 8/13/2018 10:57:00 AM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: FYI

Thanks Mark. I have not received as of this morning. Ann

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Friday, August 10, 2018 5:09 PM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: FYI

Work Folder Information
Work Folder: WF 375121
Process: FYI
Program Analyst: Whitfield, Michelle D. (NIH/OD) [E]
Due Date:
WF Subject: KEI would like HHS to investigate the failure to disclose NIH funding in patents on Vizamyl (University of Pittsburgh).
IC: od_osp
From: Cassedy, Claire
To: NLN, NFNHammersla, AnnLevinson, DanielCollins, FrancisAzar, Alex
Remarks: FYI for OSP and OGC. Assigned to OER for necessary action b5
b5

From: Mowatt, Michael (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB1EF7E2E54B4164AE34814574BDA638-MMOWATT]
Sent: 11/14/2017 4:58:44 PM
To: Sayyid, Fatima (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b9e45041bdb43719f7113a5aae27057-sayyidf]; Feliccia, Vincent (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f3a54860cb941c1abe1df786e478e00-vfeliccia]; Williams, Richard (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5f89fe4d27a43abb936bb20efeca3b9-rwilliams]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Frisbie, Suzanne (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c402740ceaad4d4f97a8c28f16fbb349-frisbies]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]; Ranjan, Mukul (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=581507f5b19448408e379fab80b9f849-mranjan]
Subject: URGENT - Fwd: Response to 82 FRN 47537
Attachments: image001.jpg; ATT00001.htm; Comments FR Zika DNA vaccine license holding statement.docx; ATT00002.htm

All,

See the attachment from Kathy Stover.

I think b5

REPLY BY 1215 with your concurrence or comments.

I will work on responses to the questions she poses below.

Thanks.

Mike

Begin forwarded message:

> **From:** "Stover, Kathy (NIH/NIAID) [E]" <kathy.stover@nih.gov>
> **Date:** November 14, 2017 at 11:14:04 AM EST
> **To:** "Billet, Courtney (NIH/NIAID) [E]" <billetc@niaid.nih.gov>, "Mowatt, Michael (NIH/NIAID) [E]" <mmowatt@niaid.nih.gov>
> **Cc:** "Haskins, Melinda (NIH/NIAID) [E]" <haskinsm@mail.nih.gov>
> **Subject: RE: Response to 82 FRN 47537**
>
> Hi all,
> Please find attached a very brief draft holding statement for potential media inquiries. A couple of questions b5
>
> b5

From: Billet, Courtney (NIH/NIAID) [E]
Sent: Monday, November 13, 2017 5:29 PM
To: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>
Cc: Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>
Subject: Re: Response to 82 FRN 47537

Thank you. Pls keep us posted on next steps

Kathy, can u pls put together a very brief holding statement for use only in event of media inquiries. I expect someone will contact us for our response **b5** **b5**

Sent from my iPhone

On Nov 13, 2017, at 5:17 PM, Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov> wrote:

> Courtney and Kathy,
>
> Note KEI's statement re perceived COI.
>
> Mike
>
> Begin forwarded message:
>
>> **From:** "Mowatt, Michael (NIH/NIAID) [E]" <mmowatt@niaid.nih.gov>
>> **Date:** November 13, 2017 at 4:55:26 PM EST
>> **To:** NIAID TTIPO <OTD@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" <jmcgowan@niaid.nih.gov>, "Harper, Jill (NIH/NIAID) [E]" <jharper@niaid.nih.gov>
>> **Cc:** "Billet, Courtney (NIH/NIAID) [E]" <billetc@niaid.nih.gov>, "Stover, Kathy (NIH/NIAID) [E]" <kathy.stover@nih.gov>, NIAID OCGR Leg <NIAIDOCGRLeg@mail.nih.gov>, "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>
>> **Subject: Response to 82 FRN 47537**
>>
>> Colleagues,
>>
>> KEI has provided comments on the FRN whose comment period ends today. They also posted a joint statement with MSF.
>>
>> The comments are posted at https://keionline.org/node/2892.
>>
>> Mike
>> **Michael R. Mowatt, Ph.D.**
>> Director, Technology Transfer and Intellectual Property Office
>>
>> **National Institute of Allergy and Infectious Diseases**
>> National Institutes of Health
>> U.S. Department of Health and Human Services
>>
>> +1 301 496 2644

NIH National Institute of
Allergy and
Infectious Diseases

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b5

From: Greene, Jaime (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E06E39F0BCD34511A92DF20C5DC8722A-GREENEJAIME]
Sent: 9/15/2017 5:10:21 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: A-325-2017
Attachments: KEI letter Nanobernetics-NIH-5Sept2017-82fr41970.pdf; Response to KEI.docx

Dear Mark,
Attached please find a draft response to KEI's objection to my intent to grant an exclusive to Nanobernetics. I have not received any other objections.

Please take a look at the response, and let me know if you have any comment.

I'd appreciate a response by September 20, 2017, the closing date of the FR Notice.
Thanks,
Jaime

Jaime Meredith Greene, M.S.
Senior Technology Transfer Manager
NCI Technology Transfer Center
9609 Medical Center Drive
Rockville, MD 20850
Telephone: 240-276-6633
Email: greenejaime@mail.nih.gov

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From: Joe Allen [jallen@allen-assoc.com]
Sent: 3/26/2018 3:17:40 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Hammersla, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87fb28aa23744c0b855ef0683ac2e8b4-hammerslaa]
Subject: IP Law 360: Bayh-Dole can be used for controlling drug prices and Jamie targets DOD

Very disappointing to see how IP Law 360 muddles two unrelated issues which will confuse its readers-- march in rights and failure to disclose a patent. But perhaps most disturbing is this about KEI's next step: " The nonprofit has also said that some of the petitions in its back pocket will actually be sent to the U.S. Army, which historically has enforced Bayh-Dole more aggressively."

You can bet that Jamie Love and KEI will be hitting DOD over the head with the King language as soon as they find a suitable test case to see if it can be forced to misuse march in rights for controlling drug prices. Here's the article

Analysis

Bayh-Dole Could Be A Drug Pricing Fix, If The Feds Want It

Share us on: By **Dani Kass**

Law360 (March 23, 2018, 6:26 PM EDT) -- As the debate over rising drug prices continues to rage, one advocacy organization is pushing the federal government to take advantage of a tool already in its belt: the Bayh-Dole Act, which allows the feds to take ownership of patents it helped fund or force companies to provide licenses for those patents.

While experts seem skeptical that the government is going to start taking patents for itself, as Knowledge Ecology International is urging, they say Bayh-Dole may just be the leverage needed to get drug companies to adjust prices on their own. However, experts cautioned against hope for rapid change, as the feds' lackluster history of enforcing the act, the control the pharmaceutical industry exerts over the government, and concerns that innovation could be stifled stack the deck against advocates.

"We're hoping that people in the oversight area — members of congress, the press, and other stakeholders — pay more attention and come to more fully appreciate the fact that the federal government has leverage that isn't being used," KEI Director James Love said.

KEI and Bayh-Dole: A Primer

When Bayh-Dole became law in 1980, it was the first time private organizations or companies — namely universities and smaller businesses — were cleared to commercialize patents that come from government funding. Previously, the patent rights went straight to the government.

But the law made sure the sponsoring agency had some oversight, especially if there were public health requirements at play that weren't being met. The ultimate remedy allowed is for the government to take over the patent's title, but the government can also force companies to license the patents out to others — called march in rights — or work out a deal to make the companies adjust their price.

KEI — which bills itself as a nongovernmental organization focused on social justice issues, namely "innovation and access to medical technologies" — has asked the National Institutes of Health to consider the most extreme step, alleging that certain companies have failed to meet disclosure requirements set out by Bayh-Dole. Those requirements mandate that companies disclose any government funding in their patent applications.

So far, the group has filed **petitions targeting patents** that cover Gilead Science Inc.'s hepatitis C drugs, Sovaldi, Harvoni, Epclusa and Vosevi; Novartis AG's leukemia drug Rydapt; and Aegerion Pharmaceuticals Inc.'s cholesterol medication Juxtapid, and the organization said other petitions are in the works. Each of these drugs has been scrutinized for its price tag, reaching between thousands and hundreds of thousands of dollars for treatment.

KEI admits that the NIH has never taken a drug's patent before, meaning their likelihood is bleak, but that doesn't mean there can't be some kind of change. For example, the organization asked that as a more moderate solution, Gilead could provide its hep C drugs to the U.S. Department of Veterans Affairs at cost.

"It's a general oversight issue of how NIH is managing taxpayer resources that are going to all these big research institutions," KEI attorney Andrew Goldman said. "It's really critical that the NIH starts treating the Bayh-Dole Act like that — knowing it's meant to protect the public and recognizing the leverage it has, and using it."

High Hopes and a Reality Check

Fellow activists at Public Citizen were quick to dub these petitions a "very important strategy" for targeting drug pricing.

"There are areas where legislation is required to reduce prices, this is not one of them," said Peter Maybarduk, who heads Public Citizen's global access to medicine program. "This is something the government could do tomorrow."

But just because the government has the power to take patents or make companies license them doesn't mean it's likely to do so, or that it would be easy, effective or consequence-free.

New York Law School associate professor Jacob Sherkow said KEI's work "highlights an uncomfortable truth: Although we'd like to think otherwise, the connection between IP and drug pricing is really, really complicated."

"Even if successful, there's no guarantee that taking title to patents covering expensive drugs would actually make them cheaper," Sherkow said. "NIH is not a drug manufacturer, and if no company is willing to cheaply manufacture and market those drugs under an NIH license, then KEI's efforts would have been for naught."

McDonnell Boehnen Hulbert & Berghoff LLP partner James DeGiulio added that these drugs are covered by several patents, so the government taking ownership wouldn't necessarily allow it to start making the drug itself.

But just the threat of taking drastic measures may be enough leverage to cause a drug company to drop prices, experts said.

"The question is, does the threat create enough pressure and public embarrassment and so forth, that it leads to some action, and that's always hard to gage," said Arti Rai, a Duke University School of Law professor who has researched Bayh-Dole extensively. "In the past there have been some attempts to use Bayh-Dole safety valves or accountability measures, and sometimes they've been successful in the sense that the entity involved has changed it's behavior."

For example, during the anthrax attacks in 2001, the government was considering enforcing the act against Bayer, in hopes of making the drug company's treatment ciprofloxacin more accessible. Under that pressure, Bayer cut it's price in half, Maybarduk said.

Rai said it's a game of measuring the threat against the consequences.

"The company knows that the government won't take the patent, but the company also knows that the government, if they wanted to, could harass them a bit," she said.

Maybarduk added that "the government has useful leverage here and careful consideration of requests like this improves the government's bargaining power to achieve better prices," he said.

Schiff Hardin LLP partner Kevin Nelson said the Bayh-Dole tactic would be "valuable in small doses," with the government possibly being able to get the prices down on certain drugs or at least for a certain group of people, like the VA request KEI has made.

This leverage, though, assumes that Gilead, Novartis, Aegerion and the to-be-named others actually have made disclosure errors, Holland & Knight LLP partner John Moran stressed. Even if they have, at most the government will likely tell them to fix it, unless there's actual evidence that a company was trying to hide something, he said. If anything, this is likely to affect one company here and there, not drug pricing on a wide scale, given how fact-specific each case is, Moran said.

If the NIH were to take a patent or demand an outside license just because of an administrative error, rather than some kind of fraud, DeGiulio warned that there would be a chilling effect stopping researchers from commercializing technologies that stem from government-funded research.

But Northeastern University School of Law professor Brook Baker argued it's time to take a chance, and that "there ought to be some teeth on this requirement," especially because often taxpayers and government agencies pay once for the research and development and then again for the drug itself.

"It's kind of a wacky system, to pay someone to charge you a monopoly price," he said. "You look in a mirror and say, why are we doing this?"

It's All Political

Multiple experts said what happens next comes down to a question of political will. While President Donald Trump's administration has said it wants to tackle drug prices, there's widespread concern it won't actually follow through.

Trump's U.S. Health and Human Services head, **Alex Azar**, came from leading the pharma powerhouse Eli Lilly and Co., which could either mean his loyalty lies with big pharma, or — as Azar said during his confirmation hearings — give him the insider knowledge to change things. U.S. Food and Drug Administration **Commissioner Scott Gottlieb** has made targeting drug prices one of his biggest goals, but he also has financial ties to big pharma.

"There's a Nixon goes to China situation going on, where [Azar and Gottlieb] can do things that would have been harder than for someone who had never been in the pharma industry," Rai said.

It's hard to bet on how this administration will align with political precedent, which DeGiulio said means it could be worth taking a shot on an idea that had a hard time gaining footing in the past.

“It’s an interesting political climate, and some unconventional mechanisms that have not had any traction in the past may have traction now,” he said.

Sherkow noted that most people who would look favorably on a request like KEI's have since left NIH or don't want to put themselves in political crosshairs. The nonprofit has also said that some of the petitions in its back pocket will actually be sent to the U.S. Army, which historically has enforced Bayh-Dole more aggressively.

Either way, it's widely acknowledged that something has to change, and experts say this is one already available way the administration could do that.

"The early indicators are that the Trump administration, not uniquely, does not plan to challenge the drug companies that way, but they're going to have to do something because people are up in arms," Maybarduk said. "Poll after poll shows people think drug pricing is a top priority. Inaction is not acceptable."

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From: Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]
Sent: 6/24/2019 5:14:35 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Pazman, Cecilia (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf35741501e247d887acd224eaf9d679-pazmance]
CC: Kirby, Tara (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2368a591fa4c4932a802e5d467fb49ed-tarak]
Subject: Fwd: Inquiry regarding 84 FR 28063 Doc 2019-12708 - Prospective Grant of Exclusive Patent License: Lutetium-177 Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors

Mark- **b5**
b5

Thanks !

From: "Claire Cassedy" <claire.cassedy@keionline.org>
Date: Monday, June 24, 2019 at 12:33:19
To: "Shmilovich, Michael (NIH/NHLBI) [E]" <michael.shmilovich@nih.gov>
Subject: Inquiry regarding 84 FR 28063 Doc 2019-12708 - Prospective Grant of Exclusive Patent License: Lutetium-177 Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors

Dear Mr. Shmilovich,

I am writing in reference to the Federal Register notice (84 FR 28063 Doc 2019-12708) regarding, "Prospective Grant of Exclusive Patent License: Lutetium-177 Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors," for which you are listed as the contact for inquiries. I was hoping you could provide me with some further information regarding the status of the technologies.

1. At what stage of development are the inventions listed?
2. Has the government funded any clinical trials relevant to these technologies?
3. If the government has provided funding, how much has been spent by the government on these trials? Can you provide NCT numbers?
4. How many years of exclusivity have been offered in this agreement, and what will the royalty rate be?
5. Regarding the company to receive the licenses, Molecular Targeting Technologies, Inc. are any former NIH employees associated with the company?

Thank you in advance for your assistance in this matter.

Best Regards,
Claire Cassedy

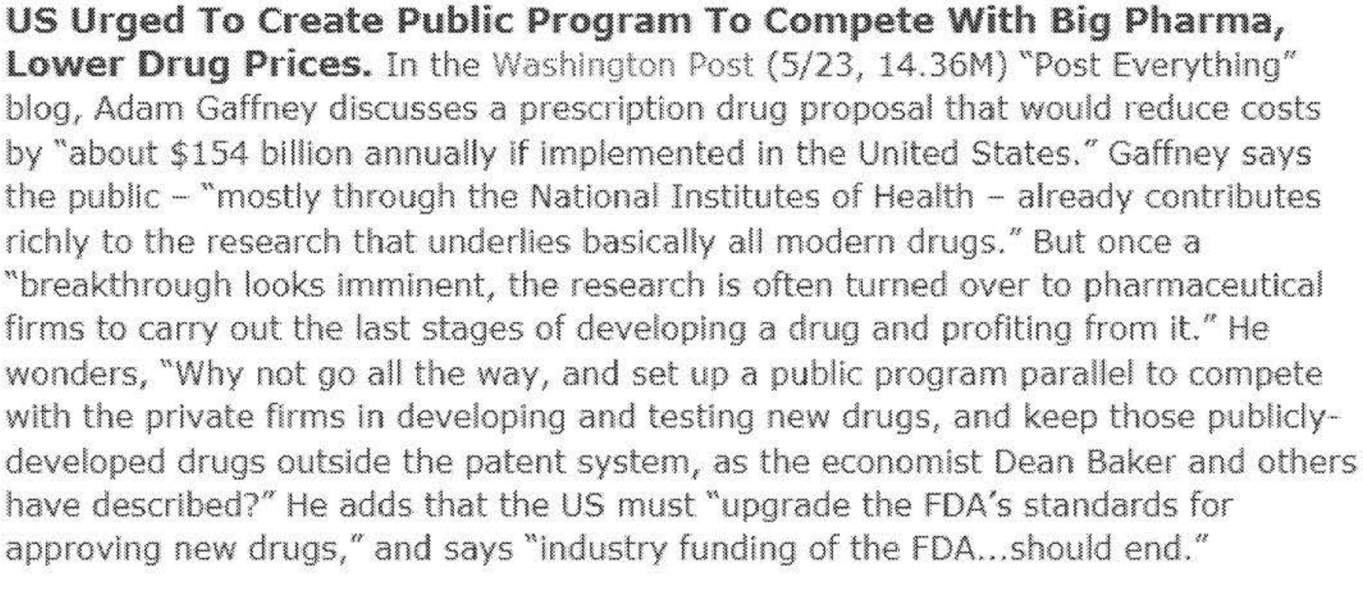
--
Claire Cassedy
Knowledge Ecology International
1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
Tel.: 1.202.332.2670

From: Koniges, Ursula (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D5AE2C3139654BC0B9B95718D516310B-KONIGESUM]
Sent: 5/24/2018 1:27:53 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Dodson, Sara (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=985a956eaa0d4945bdcfd8ea30947d68-dodsonse]
Subject: NIH News – Drug Pricing Policies Opinion Piece in WaPo

This morning's NIH News summary included a WaPo perspective piece on drug pricing policy, which notes KEI's writing among that of others (see link highlighted in yellow):

> "The public — mostly through the National Institutes of Health — already contributes richly to the research that underlies basically all modern drugs. But once a breakthrough looks imminent, the research is often turned over to pharmaceutical firms to carry out the last stages of developing a drug and profiting from it. Why not go all the way, and set up a public program parallel to compete with the private firms in developing and testing new drugs, and keep those publicly-developed drugs outside the patent system, as the economist Dean Baker and others have described? These new drugs could immediately be manufactured cheaply as generics. Research could be directed toward the drugs that are most needed, not the most profitable, while testing would be performed by scientists without conflicts of interest."

The NIH News summary has the following summary of the piece:



US Urged To Create Public Program To Compete With Big Pharma, Lower Drug Prices. In the Washington Post (5/23, 14.36M) "Post Everything" blog, Adam Gaffney discusses a prescription drug proposal that would reduce costs by "about $154 billion annually if implemented in the United States." Gaffney says the public – "mostly through the National Institutes of Health – already contributes richly to the research that underlies basically all modern drugs." But once a "breakthrough looks imminent, the research is often turned over to pharmaceutical firms to carry out the last stages of developing a drug and profiting from it." He wonders, "Why not go all the way, and set up a public program parallel to compete with the private firms in developing and testing new drugs, and keep those publicly-developed drugs outside the patent system, as the economist Dean Baker and others have described?" He adds that the US must "upgrade the FDA's standards for approving new drugs," and says "industry funding of the FDA...should end."

From: Jambou, Robert (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FF42A9FA39824980AA9E36AF49E56CBC-JAMBOUR]
Sent: 8/10/2018 3:28:28 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: KEI FOIA reviewed

Hi Mark,

I have completed the review of the redactions done by the NHLBI. As stated earlier, **b5**

b5

Thanks,

Bob J.

From: Mowatt, Michael (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB1EF7E2E54B4164AE34814574BDA638-MMOWATT]
Sent: 11/13/2017 9:18:30 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]; Frisbie, Suzanne (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c402740ceaad4d4f97a8c28f16fbb349-frisbies]
Subject: FW: KEI, MSF Comments Relating to Prospective Grant of Exclusive Patent License: DNA-Based Vaccine for Prevention of Zika Virus Infection
Attachments: KEI_PaxVax_111317.pdf; KEI MSF NIH Zika Vaccine License Comments November 2017.pdf

Mark,

Amy just passed this along to me.

No responses to FRN other than these and KEI's previous two emails.

Mike

From: Petrik, Amy (NIH/NIAID) [E]
Sent: Monday, November 13, 2017 4:06 PM
To: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Salata, Carol (NIH/NIAID) [E] <csalata@niaid.nih.gov>; Feliccia, Vincent (NIH/NIAID) [E] <vfeliccia@niaid.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>
Cc: Contreras, Vince (NIH/NIAID) [E] <vince.contreras@nih.gov>
Subject: FW: KEI, MSF Comments Relating to Prospective Grant of Exclusive Patent License: DNA-Based Vaccine for Prevention of Zika Virus Infection

Hi everyone,

Just received, FYI.

Thanks,
Amy

From: Andrew S. Goldman [mailto:andrew.goldman@keionline.org]
Sent: Monday, November 13, 2017 3:59 PM
To: Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>
Cc: Jamie Love <james.love@keionline.org>; Kim Treanor <kim.treanor@keionline.org>; Jennifer Reid <Jennifer.Reid@newyork.msf.org>
Subject: KEI, MSF Comments Relating to Prospective Grant of Exclusive Patent License: DNA-Based Vaccine for Prevention of Zika Virus Infection

Dear Dr. Petrik:

On behalf of Knowledge Ecology International (KEI) and Médecins Sans Frontières (MSF), please see the two attached documents:

(1) Comments submitted on behalf of both KEI and MSF on the proposed exclusive license of a Zika vaccine referred to in FR Vol. 82, No. 196 on October 12, 2017; and

(2) Additional comments of KEI on potential conflicts of interest that create a compelling need for increased transparency with regard to the proposed license, and on additional proposals to limit the scope of exclusive rights.

If you have any questions with regard to these two documents, please let me know.

Sincerely,

Andrew S. Goldman
Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
www.keionline.org

KEI
KNOWLEDGE ECOLOGY
INTERNATIONAL

Additional Comments by KEI on the PaxVax License, FR Doc. 2017–21986 Filed 10–11–17; as noted in Federal Register Vol. 82, No. 196, October 12, 2017.

KEI has a joint submission with MSF that describes our opposition to an exclusive license to PaxVax for the NIAID Zika vaccine patents, and which proposes safeguards in such a license, if the NIAID decides to use an exclusive license, despite our concerns.

This letter supplements the joint letter with KEI's deals with two sets of concerns. First, KEI wants to note that the appearance of potential conflicts of interest provides an additional compelling reason for more transparency. Second, KEI proposes additional limitations on the scope of exclusive rights.

1. The appearance of potential conflicts of interest provides additional reasons to be more transparent as regarding the proposed license.

There is at a minimum the appearance of a conflict of interest between interested parties at PaxVax and various parties within the federal government.

Ken Kelley, the founder, former CEO and Director on the Board of PaxVax from 2007-2015 has, since 2015, been working as,

> "a White House Presidential Executive Fellow, and Senior Advisor to the Biomedical Advanced Research and Development Authority (BARDA) and the National Institute of Allergy and Infectious Disease Vaccine Research Center (NIAID/VRC), both within the U.S. Department of Health and Human Services. He is working on special projects within global biosecurity including the U.S. Government's response to the Zika Virus outbreak, aligning vaccine development efforts across agencies throughout the U.S. Government, and engaging with the new global vaccine development fund, the CEPI (Coalition for Epidemic Preparedness Innovations)."[1]

In addition to the interests of Mr. Kelley, the grant of an exclusive license of this technology to PaxVax would likely also be in the interest of Cerberus Capital Management, which acquired majority interest in PaxVax in late 2015.[2] The co-founder and Chief Executive Officer of Cerberus Capital Management is Stephen Feinberg.[3] Mr. Feinberg was a major contributor to Donald Trump's presidential campaign, giving an estimated $2.2 million to groups backing his candidacy as well as hosting a fundraiser for the campaign, and is reportedly advising the Administration on matters concerning national security.[4]

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[1] https://www.linkedin.com/in/kennethjkelley/

The appearance of a potential conflict of interest creates a compelling need for transparency regarding the terms of and the rationale for an exclusive license for this publicly financed technology, and further supports the call made in our joint submission with MSF for a hearing on this proposed license.

2. Additional proposals to limit the scope of exclusive rights.

In addition to the four proposals in the joint MSF/KEI letter to limit the exclusive rights in a license to PaxVax, KEI provides the following suggestions.

1. The term of the exclusive licence to PaxVax should be no longer than 5 years, subject to successive three year extensions upon a finding that the PaxVax price is reasonable given the public sector role in funding the development of the vaccine, and that access to the vaccine is acceptable.

2. Assuming the vaccine candidate is already in a government funded phase 2 trial and PaxVax is solely funding the phase 3 trial, the exclusivity shall no longer be in effect if the vaccine generates more than $500 million in sales globally, assuming this is at least more than three times the expected costs of phase 3 testing for the vaccine. If the NIH funds the phase 3 trial, a lower threshold will be appropriate, such as $100 million.

Knowledge Ecology International
November 13, 2017

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[2] https://pitchbook.com/newsletter/cerberus-acquires-paxvax-majority-interest-for-105m

[3] http://www.cerberuscapital.com/team/stephen-a-feinberg/

[4] https://www.bloomberg.com/news/articles/2017-04-03/billionaire-feinberg-might-keep-cerberus-stake-in-new-trump-role, and https://www.nytimes.com/2017/02/15/us/politics/trump-intelligence-agencies-stephen-feinberg.html.

Doctors Without Borders/Médecins Sans Frontières and Knowledge Ecology International Comments to the National Institutes Notice of Prospective Grant of Exclusive Patent License: DNA-Based Vaccine for Prevention of Zika Virus Infection

November 13, 2017

Table of Contents

Introduction 2

Overview 2

We object to the granting of this exclusive license for development of Zika vaccine candidates for the following reasons: 4

- There is insufficient information provided regarding the technology to satisfy requirements under the Bayh Dole Act and Regulations 4
- There is considerable evidence that the grant of exclusivity is not a reasonable and necessary incentive to promote innovation and further development of a Zika vaccine. 5
- The grant of patent exclusivity can hinder innovation for Zika vaccines and doesn't allow research strategies that promote collaboration and focus on neglected medical needs. 7
- An exclusive license can be a barrier to ensuring a Zika vaccine will be available and affordable to all who need it. 8

A better way to promote U.S. government funded innovation: open non-exclusive licenses with terms and safeguards for patient-driven innovation and future affordable access 9

If an exclusive license is granted, we recommend the following limitations on the scope of rights, safeguards on pricing and affordability, and other terms to advance the public interest. 10

Conclusion 11

Introduction

Doctors Without Borders/Médecins Sans Frontières (MSF) and Knowledge Ecology International (KEI) provide the following comments regarding the Notice from the National Institutes of Health (NIH) regarding the Prospective Grant of Exclusive Patent License: DNA-Based Vaccine for Prevention of Zika Virus Infection.[1]

We object to the grant of an exclusive patent license and urge the United States government to consider the negative impact an exclusive agreement will have on the development, affordability and availability of a Zika vaccine, which is needed for people affected by the Zika virus in the United States and worldwide.

Our objections cover the following points.

1. There is a lack of transparency regarding the proposed technology to be licensed, and the extent the public sector has already and will going forward subsidize the development of one or more vaccines covered by the license.
2. The NIH has not demonstrated an appropriate justification for the grant of an exclusive license, under the standards set out in 35 USC 209.
3. If the NIH does go ahead with an exclusive license, the license should at a minimum include provisions to safeguard affordable access, and limit the scope of the exclusive rights to that reasonably necessary to induce the necessary investment to bring the inventions into practical application, as defined in 35 USC 201(f).

Based upon the objections described herein, and the lack of sufficient information provided in the Federal Register notice, we request that the NIH consider a non-exclusive license or provide additional information relevant to evaluating this proposed licensing agreement and provide opportunities to consider the proposed license based on this information through a hearing or subsequent comment period.

Overview

MSF is an international medical humanitarian organization working in nearly 70 countries. Every year, MSF vaccinates tens of thousands of children, delivering about 5.3 million doses of vaccines and immunological products in 2015 alone. We need biomedical innovations that improve medical outcomes and are accessible and affordable, including for prevention and treatment of global health emergencies. We hope to use an effective Zika vaccine in our medical operations in the future. MSF, Ministries of Health and people around the world will only be able to benefit from the U.S. government investment if the resulting vaccine is effective, safe, available, affordable and suitably adapted to the resource-limited settings where most people affected by Zika virus live. Through our work, MSF witnesses the everyday impact of having limited or no access to medicines, diagnostics and vaccines, due to the lack of innovation on essential, suitably adapted and affordable medical tools in the contexts and populations where they are most needed.

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[1] Federal Register. Department of Health and Human Services, National Institutes of Health. Notice of Prospective Grant of Exclusive Patent License: DNA-Based Vaccine for Prevention of Zika Virus Infection. Vol 82, No 186, 12 October 2017. Available from: https://www.federalregister.gov/documents/2017/10/12/2017-21986/prospective-grant-of-exclusive-patent-license-dna-based-vaccine-for-prevention-of-zika-virus#addresses

Knowledge Ecology International (KEI) is a not for profit non-governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources. KEI is focused on social justice, particularly for the most vulnerable populations, including low-income persons and marginalized groups. KEI is particularly concerned about the pricing and affordability of drug, vaccines and other medical technologies, and the management of government owned patents and other knowledge based assets derived from public sector funded research and development.

Our organizations recognize the need to reward innovation and finance research and development (R&D). We thank the U.S. government for its funding and leadership in Zika vaccine research and welcome the investment of US government resources in research on Zika vaccine candidates. We also encourage the NIH to grant licenses to entities that can help bring effective vaccines to market in a timely way. Our concerns are on the terms of such licenses, given the public interest in affordability and access to products and services based upon inventions owned by the NIH and the public health need for affordable, effective and appropriately developed Zika vaccines.

Under the Bayh-Dole Act, there are restrictions on the use of exclusive licensing of patents owned by the federal government, including those set out in 35 USC 209. These restrictions are designed to limit the grant of monopolies on federally owned patents to only those cases where an exclusive license is necessary to induce investments in the development of a product. The Bayh-Dole Act also requires agencies to limit the scope of such rights when exclusive licenses are used, to minimize the harm to competition.

In this case, the National Institute of Allergy and Infectious Diseases (NIAID) seeks to give PaxVax an exclusive license on inventions which have not been disclosed, but which we believe are related to more than one Zika DNA vaccine candidate. We believe at least one of the DNA vaccine candidates has already entered phase 2 testing, at taxpayer expense. If the vaccine is successful, we anticipate that PaxVax will received several benefits unrelated to patent rights.

The benefits that PaxVax will receive outside of the patent rights include:

1. Tax credits under the orphan drug tax credit, currently equal to 50 percent of the costs of conducting trials (net of any subsidy from the NIH).
2. Seven years of exclusive rights under the Orphan Drug Act.
3. 12 years of exclusive rights on test data, which may or may not extend to the NIAID funded trials on the vaccines, depending upon the content of the licensing and other contractual agreements with the NIAID.
4. A priority review voucher (most recently sold for $150 million 2017Q3).
5. A period of years during which no other company can realistically register a biosimilar vaccine, regardless of the patent status.

We believe this collective set of subsidies and exclusive rights associated with regulatory test data and orphan disease status make the use of an exclusive license, particularly one that would extend the monopoly until the year 2037 or later, unnecessary and illegal under 35 USC 209.

We are also concerned about the affordability of and access to the vaccine, in the United States, and worldwide. These concerns exist even under non-exclusive license to the patents, if PaxVax is able to obtain exclusive rights to test data and/or orphan drug exclusivity.

PaxVax has a history of marketing vaccines to travelers and tourists, and may not be willing or able to scale access in countries where the need is the greatest.

A vaccine that is not appropriately developed or a vaccine without appropriate measures to ensure access is a missed opportunity to make maximal use of limited US government resources. The next step in the Zika vaccine development process, including its licensing and technology transfer strategy, needs to ensure that U.S. government funding and leadership in vaccine R&D results in a vaccine that is effective and accessible for all patients in need in the U.S. and globally, including the most neglected. As the latest Ebola outbreak in West Africa should constantly remind us, diseases have no borders in a globalized world. Without a global research and access strategy for the Zika vaccine, the disease cannot be prevented in the most at-risk populations.

We object to the granting of this exclusive license for development of Zika vaccine candidates for the following reasons:

1. There is insufficient information provided regarding the technology to satisfy requirements under the Bayh Dole Act and Regulations

We believe that the Federal Register notice of October 12, 2017 fails to meet the requirements of 35 U.S.C. 209(e) and 37 CFR 404.7 in failing to provide sufficient detail regarding the technology to permit meaningful and substantive comment by the public.

35 U.S.C. 209(e) requires that "No exclusive or partially exclusive license may be granted under section 207(a)(2) unless public notice of the intention to grant an exclusive or partially exclusive license on a federally owned invention has been provided in an appropriate manner at least 15 days before the license is granted, and the Federal agency has considered all comments received before the end of the comment period in response to that public notice." 37 CFR 404.7 requires that the notice identify the technology and prospective licensee.

The Federal Register notice in this instance does not provide sufficient information regarding the technology to even answer basic questions regarding which type of Zika vaccine this particular technology is. The notice provides a Department of Health and Human Services (HHS) reference number and a provisional patent application number for "Zika virus vaccines," and describes certain characteristics of the vaccine in question, including that it is a DNA-based candidate referred to in a Federal Register Notice published on December 12, 2016.

That Federal Register Notice of December 12, 2016 in fact refers to two separate vaccine candidates: (1) VRC-ZKADNA085-00-VP (referred to as VRC5288); and (2) VRC-ZKADNA090-00-VP (referred to as VRC5283). VRC5288 has been in clinical trials[2]; likewise, VRC5283 has also been in clinical trial.[3]

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[2] https://clinicaltrials.gov/ct2/show/NCT02840487.

[3] https://clinicaltrials.gov/ct2/show/NCT02996461 and https://clinicaltrials.gov/ct2/show/NCT03110770.

It is impossible to know which of these two are the candidate referred to in the Federal Register notice of October 12, 2017. Moreover, NIH has failed to respond to two separate emails requesting clarification on this matter. An email on October 25, 2017 from Kim Treanor of Knowledge Ecology International to Dr. Petrik of NIH, who is described in the Federal Register notice as the contact for all inquiries related to the contemplated exclusive license, and asked a series of questions to help clarify basic facts about this invention; having received no response, Ms. Treanor sent a follow-up email on November 7, 2017, asking once again for responses to her prior questions, explicitly adding a question as to whether the subject invention of the proposed exclusive license was VRC-ZKADNA090-00-VP.[4] KEI also tried to reach out to Dr. Petrik via phone. To date, KEI has not received any response to any of these queries.

Without clarity as to what the invention is that HHS proposes to license, and without access to the patent application, the public does not have access to basic facts that are critical to providing meaningful comment.

We ask the NIH to publish an explanation of why an exclusive license has been deemed to be "reasonable and necessary" and if so, if the restrictions on the scope of exclusivity are limited to that "reasonably necessary" and includes appropriate safeguards. The NIH should at a minimum provide the following information to the public:

1. The intellectual property that the NIH intends to license to PaxVax, including (1) United States Provisional Patent Application 62/396,613, including in particular the patent claims that will be licensed.
2. Whether any other potential vaccine developers expressed interest in this license
3. The estimated spending to date by the NIH or any other public US institution in the development of this vaccine candidate
4. The estimated spending to date by PaxVax in the development of this vaccine candidate
5. The estimated costs to further develop this vaccine candidate through market approval
6. Identification of any clinical trials using the patented inventions, including the trial name, ClinicalTrials.Gov identification number, the number of patients enrolled, and the trial phase.

2. There is considerable evidence that the grant of exclusivity is not a reasonable and necessary incentive to promote innovation and further development of a Zika vaccine.

Based on our analysis of available information, granting an exclusive license to patents on a potential Zika vaccine to PaxVax is contrary to the provisions of 35 U.S.C. 209(a)(1). According to U.S. law, the United States government may grant an exclusive or partially exclusive license "only if" the exclusivity is "a reasonable and necessary incentive to call forth the investment capital needed to bring the invention to practical application; or otherwise promote the invention's utilization by the public." In other words, the U.S. government cannot grant exclusive licenses in cases where the exclusive rights are not reasonable and necessary for the practical application and utilization of the invention.

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[4] Emails on file with Knowledge Ecology International.

Before an exclusive license is granted, PaxVax or any other potential recipient of an exclusive license and the National Institutes of Health have the burden of proving that these exclusive rights are necessary.

Pharmaceutical companies often assert that exclusivity is necessary to recoup investments and risk associated with the research and development process, as well the opportunity cost to work on a given technology. However, we argue that this exclusivity is unnecessary to promote innovation and the further development of these vaccine candidates given:

a. The funding and resources that the U.S. government has already dedicated to the vaccine candidates have significantly reduced the need for investment and lowered the risks to the company. This is particularly true for the vaccine candidate C-ZKADNA090-00-VP (Zika virus wildtype DNA vaccine), which is now in phase 2 testing, funded by NIAID[5], if this is one of the technologies to be licensed. (We have asked NIAID to at least confirm this is one of the candidates to be licensed, but have not received a response, and discuss this in further detail below).

b. PaxVax and any other vaccine developer that further develops this vaccine candidate are eligible to receive additional funding from the federal government. (We have asked the NIH about future funding prospects, but have not received a response).

c. Any investments by PaxVax in the clinical trials for the vaccine are eligible for an orphan drug tax credit. Under current law, the value of the credit would be equal to 50 percent of the cost of qualifying trials.[6] We believe the credit would be available even for trials conducted outside of the United States.

d. The company that registers the vaccine will be eligible to receive a Food and Drug Administration (FDA) Priority Review Voucher (PRV) for neglected diseases, without any product access conditions attached.[7] Since August 2015, the known prices for traded PRVs have ranged from $125 to $350 million. We note, for example, that PaxVax reportedly sold a PRV they were awarded for a cholera vaccine approval for $200 million,[8] and that there was a reported sale of a PRV for $150 million sales in 2017 Q3.[9]

e. The Zika vaccine candidate is likely to benefit from the seven years of marketing exclusivities attached to an orphan drug designation, which is available for any vaccine that is used to treat fewer than 200,000 persons annually in the United States. If the U.S. market is larger than 200,000, there is even less reason to grant an exclusive license, given other barriers to competition and the larger size of the U.S. market.

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[5] https://clinicaltrials.gov/ct2/show/NCT03110770

[6] There may be modifications to the credit in the current tax reform legislation.

[7] Brock W, Cohen R, Cone J, McKenna L. The Zika loopholes. Politico. 25 March 2016. Available from: http://www.politico.com/agenda/story/2016/03/the-right-way-to-encourage-companies-to-develop-a-treatment-for-zika-000079

[8] BioPharma Dive. GSK uses priority voucher to file HIV combo. 2 June 2017. Available from: https://www.biopharmadive.com/news/gsk-uses-priority-voucher-to-file-hiv-combo/444131/

[9] Alexander Gaffney, RAC, Michael Mezher, Zachary Brennan, Regulatory Explainer: Everything You Need to Know About FDA's Priority Review Vouchers, October 2, 2017. Available from: http://www.raps.org/Regulatory-Focus/News/2015/07/02/21722/Regulatory-Explainer-Everything-You-Need-to-Know-About-FDA%E2%80%99s-Priority-Review-Vouchers/

f. As vaccines are included among the definition for biologic products under 42 U.S.C. 262(i), PaxVax would also benefit from twelve years of exclusive rights to market the vaccine under 42 U.S.C. 262(k)(7)(A), barring competitors from gaining market approval through reliance upon evidence that a vaccine is safe and effective. The 12 years of exclusive rights in test data are, wholly apart from any patent protection that may or may not exist, a significant barrier for entry by a biosimilar product, and would require a follow on biosimilar product to replicate costly, time consuming and potentially unethical clinical trials.[10]

g. PaxVax and other vaccine developers may also receive other resources provided by other countries. For example, the funds and resources that will be made available to accelerate vaccine development for emerging infectious diseases with the recently launched Coalition for Epidemic Preparedness Innovations (CEPI) that multiple governments, philanthropies like the Bill & Melinda Gates Foundation and the Wellcome Trust, and MSF are members of.

3. The grant of patent exclusivity can hinder innovation for Zika vaccines and doesn't allow research strategies that promote collaboration and focus on neglected medical needs.

a. While the NIAID has not provided the public with any details of the patent claims for the proposed license, patents can be a threat to the timely development of and access to affordable versions of newer vaccines.[11] We are concerned that an exclusive license will allow PaxVax to block other companies from developing DNA vaccines that would be less expensive, more effective, or both.

b. The grant of exclusivity does not ensure that the Zika vaccine development process will target the populations most in need. PaxVax will be allowed to pursue research strategies to maximize use of the vaccine candidate in profitable markets, like the U.S. or the travelers market, limiting or excluding clinical development of competing research agendas that should include a broader and diverse geographical scope to ensure any resulting vaccine is effective and useful in the full range of populations who may need this vaccine.[12]

c. The grant of exclusivity does not ensure that a vaccine will be developed or that it will adhere to a timely development process. The example of promising results of clinical trials of rVSV Ebola vaccine that MSF supported shows the importance of government funding and leadership for vaccine development. It also shows how the Canadian government's exclusive licensing was unnecessary and tragically delayed urgently needed innovation. It was thanks to initial studies at a Canadian government laboratory that the VSV-EBOV vaccine was confirmed as potentially effective against Ebola. Despite the fact that the government licensed this vaccine to a U.S. company, NewLink, four years before the West African Ebola outbreak, the project stalled and the vaccine was not made available to people at risk for more than five years. If at least phase 1 clinical trials had been conducted prior to the most recent outbreak, the vaccine could have been deployed during the emergency and potentially helped save lives. This wasted opportunity and failure to advance the vaccine's development nevertheless netted NewLink more than $63.5M profit when they sold the rights to pharmaceutical company Merck during the most critical phase of the outbreak. A non-exclusive license could have allowed the Canadian government, either prior to or during the outbreak, to take more decisive action to encourage or require the timely testing and development of the vaccine.

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[10] See, e.g.: Emerging Health Care Issues: Follow-on Biologic Drug Competition, Federal Trade Commission Report, June 2009.

[11] MSF. A Fair Shot for Vaccine Affordability. September 2017. Available from: https://www.msfaccess.org/vaccine-ip-report.

[12] Adams P, Nutt C. A Zika Vaccine, but for Whom? New York Times. 28 December 2016. Available from: https://www.nytimes.com/2016/12/28/opinion/a-zika-vaccine-but-for-whom.html?_r=0

4. An exclusive license can be a barrier to ensuring a Zika vaccine will be available and affordable to all who need it.

The high price of vaccines is already a key medical and operational challenge for MSF and many governments. By 2014 the price to fully vaccinate a child in the poorest countries of the world was 68 times more expensive than it was in 2001.[13] The price in other countries is even higher. Many countries, especially countries considered middle-income economies, are often unable to afford new high-priced vaccines that prevent countless deaths from vaccine-preventable diseases such as childhood pneumonia.

Before granting a license on U.S. government-owned rights, the U.S. government should ensure that the license will ensure that the "benefits" of the invention will be "available to the public on reasonable terms," a requirement of 35 U.S.C. § 201(f). Granting an exclusive license to a vaccine manufacturer will not only fail to ensure any resulting vaccine is available on reasonable terms, but can also become a significant barrier to the future availability and affordability of the vaccine.

As the vaccine development has been publicly financed by the U.S. government, the price of any resulting vaccine should be closely aligned with production costs. Yet, an exclusive license to PaxVax will allow the company to charge high prices based on what their targeted markets will bear regardless of actual costs. Based on our experience, leaving these decisions exclusively to a pharmaceutical company may not lead to appropriate public health outcomes.

We hope PaxVax commits to and implements an appropriate access and manufacturing strategy, but also note that PaxVax does not have an established record in making vaccines available in disease-endemic countries. PaxVax currently has two approved vaccine products, both for disease primarily affecting people in developing countries. One is Vaxchora, a vaccine for cholera that earned PaxVax a US FDA priority review voucher (PRV) for neglected diseases, despite the fact that "the effectiveness of Vaxchora has not been established in persons living in cholera affected areas."[14]

An exclusive license will also be barrier to competition in the manufacturing and supply of the technology, as it will allow PaxVax to exclude other manufacturers from producing and selling the technology.

Promoting competition is the best tool to ensure affordability as well as ensuring sufficient manufacturing and supply of any resulting vaccine. MSF and patients have repeatedly experienced the consequences of what happens when a single supplier discontinues manufacturing of an effective and needed product for conditions affecting neglected populations.[15]

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[13] MSF. The Right Shot: Bringing down barriers to affordable and adapted vaccines, 2nd ed. January 2015. Available from: https://www.msfaccess.org/our-work/vaccines/article/2345

[14] FDA. FDA approves vaccine to prevent cholera for travelers. 10 June 2016. Available from: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm506305.htm.

A better way to promote U.S. government funded innovation: open non-exclusive licenses with terms and safeguards for patient-driven innovation and future affordable access

An exclusive license fails to address the need for an innovation strategy that put the needs of all patients and vaccine providers at the center of the biomedical innovation system.

We recommend that the U.S. government consider an open licensing and technology transfer strategy to allow PaxVax and a variety of vaccine developers and researchers to test and further develop this vaccine, promoting a variety of scientific, research, development, business and delivery approaches.

The licensing of this technology should include safeguards to ensure that the development will be patient-driven and that any resulting vaccine will be safe, effective, appropriately available and affordable to all people in need. We also recommend that the U.S. government make the terms and conditions of the license publicly available to allow for appropriate review, accountability and implementation of the safeguards created.

An open, non-exclusive license not only ensures that multiple companies can move towards developing the product, but can ensure that if one company fails to meet milestones or advance development, the patent holder (the US government) can move on to others and without having to go through the onerous and possibility litigious process of terminating a license, granting a march-in request or testing the boundaries of allowing third parties to produce a vaccine under the federal government's royalty free right in the license.

A non-exclusive license allows several vaccine developers to pursue different research, regulatory and development strategies of the vaccine candidate, and also can reduce the negative health impact of research stalled or delayed by a single researcher strategy. For example, in the case of the rVSV Ebola vaccine highlighted above, had the Canadian government granted an open license, governments and medical service providers such as MSF – and, most importantly, patients in need – would not have been dependent on the development timeline of only one company.

An open license allows several companies and vaccine researchers to test the effectiveness and safety of the technology in a variety of settings, including pursuing research strategies that target the needs of neglected populations due to expectation of limited profitability and/or knowledge gaps on Zika epidemiology in Africa.

An open license allows several companies to manufacture a resulting vaccine and reduces the public health liability created by a single manufacturer that decides to stop manufacturing or is not able to meet the global demand of a successfully developed Zika vaccine.

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[15] See for example, MSF. Snakebite: How Sanofi slithered its way out of the neglected antivenom market. July 2015. Available from: *https://www.msfaccess.org/sites/default/files/NTDs_Brief_FavAfrique_ENG_2015.pdf*

An open license may facilitate the emergence of competition in the manufacturing and supply of Zika vaccines, which is ultimately the best tool to promote affordability.

The NIH has extensive experience in engaging in open licenses. Many of the licenses the NIH grants are non-exclusive; in FY 2015, of 275 license agreements executed, 262 were non-exclusive.[16] In FY 2016, the NIH issued 279 licenses, and 235 were non-exclusive.[17] This includes vaccine product development. Consider for example the example of a non-exclusive licensing approach applied for the success development and manufacturing of a rotavirus vaccine.[18] Another example that of a dengue vaccine developed by NIAID and licensed non-exclusively to at least seven licensees, "enhancing the commercialization" of the product in multiple regions including high-income and developing countries.[19]

If an exclusive license is granted, we recommend the following limitations on the scope of rights, safeguards on pricing and affordability, and other terms to advance the public interest.

If, despite our opposition, the NIH intends to grant an exclusive license to PaxVax or any other manufacturer, the terms of the license should at a minimum include conditions to ensure affordable access to any resulting vaccine for all who need it.

In particular, we ask the NIH to include, at a minimum, the following safeguards on pricing and affordability:

1. PaxVax must agree to disclose the steps it will take to enable the timely registration and availability of the vaccine at an affordable price in the United States and in every county with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC)/ World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.

2. PaxVax must agree to make the vaccine available to the public in the U.S. at publicly disclosed prices no higher than the median price charged in the seven countries with the largest GDP which have per capita incomes of at least half that of the U.S.

3. The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the vaccine from competitive suppliers, including

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[16] NIH. Combine NIH-wide annual reporting on technology transfer activities FY 2015. Available from: https://www.ott.nih.gov/sites/default/files/documents/pdfs/AR2015.pdf

[17] Annual Report, FY 2016, NIH Technology, Transfer Activities. Available from: https://www.ott.nih.gov/sites/default/files/documents/pdfs/AR2016.pdf

[18] NIH.Rotavirus Vaccine: NIH Office of Technology Transfer. Available from: https://www.ott.nih.gov/sites/default/files/documents/pdfs/casestudy13.pdf

[19] NIH. NIH Technology Transfer Activities Annual Report FY 2016. Available from: https://www.ott.nih.gov/sites/default/files/documents/pdfs/AR2016.pdf

technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the vaccine.

4. PaxVax must provide annual public reports on the R&D costs incurred, the manufacturing costs of the vaccine, the number of units sold in every country, as well as the status of any patents on the vaccine and all country registrations. Note, such reports are not constrained by the limits on public disclosure for plans referred to in 35 U.S.C. 209(f).

KEI is proposing additional conditions on pricing in a separate letter that are specific as regards limitations on exclusivity.

Conclusion

At a time when the high prices of life-saving medical tools, including hepatitis drugs, biologics and vaccines have become a major barrier to effective medical care worldwide and medicines are being rationed because of high prices in the U.S. and around the world, it is concerning to see the U.S. government considering a license that will lock in a monopoly on an important NIH invented and developed vaccine to one company, until 2037, without any safeguards regarding affordable access to the resulting vaccine.

Instead of creating new exclusivities for pharmaceutical companies by giving away exclusive rights on publicly funded innovation, the U.S. government should pursue R&D strategies that promote open and collaborative innovation and ensure affordable access to resulting products.

The Bayh-Dole Act has restrictions on the grant of exclusive licenses in order to protect the public from harm caused by the unnecessary grant to monopolies. Among those restrictions are a requirement for a finding that an exclusive license is a necessary measure to secure development of a vaccine, and that rights have been limited to only that reasonable necessary to accomplish that goal, consistent also with an obligation to ensure that the invention is "available to the public on reasonable terms."

MSF and KEI have provided ample evidence that an exclusive license is not necessary in this case, particularly as regards the vaccine candidate that is currently in phase 2 testing. When an exclusive license on a federally owned invention is not reasonably necessary, it is not allowed under the Bayh-Dole Act. The NIH has failed to provide sufficient information and rationale to address these concerns.

We ask that the NIH instead consider a non-exclusive license. We have also asked that if an exclusive license is indeed used, that the license include limitations on the scope of the rights granted, and specific, clear and actionable safeguards as regards the pricing of and access to the vaccine.

If the NIH intends of purse an exclusive license, they should first release necessary and relevant information relevant to evaluating the license, then provide a new comment period, and hold a public hearing on the proposed license.

For follow up, please contact Jennifer Reid at MSF (Jennifer.Reid@newyork.msf.org), or James Love (James.Love@KEIonline.org) or Andrew Goldman (Andrew.Goldman@KEIonline.org) at KEI.

Doctors Without Borders/Médecins Sans Frontières

Knowledge Ecology International

From: Jorgenson, Lyric (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=JORGENSONLA]
Sent: 3/6/2017 3:05:43 PM
To: Volkov, Marina (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=nimh/cn=mvolkov]; Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
CC: Fennington, Kelly (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=FENNINGTONKNEW]
Subject: FW: MLR final edits to BRAIN DRug pricing
Attachments: Doggett-51member-MarchIn-11Jan2016.pdf; ATT00001.htm; HHS response to Doggett page 1.jpg; ATT00002.htm; HHS response to Doggett page 2.jpg; ATT00003.htm; Drug Pricing OSP edits MLR 2.docx; ATT00004.htm

Did you guys hear back from Carrie on this? If not, I'll review now.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Saturday, March 04, 2017 11:42 AM
To: Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>
Cc: Carr, Sarah (NIH/OD) [E] <CarrS@OD.NIH.GOV>; Volkov, Marina (NIH/OD) [E] <mvolkov@od.nih.gov>; Dodson, Sara (NIH/OD) [E] <sara.dodson@nih.gov>; Baden, Elizabeth (NIH/OD) [E] <badenem@od.nih.gov>; Hagedorn, Caroline (NIH/OD) [E] <caroline.hagedorn@nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <jorgensonla@od.nih.gov>; Fennington, Kelly (NIH/OD) [E] <FenningK@OD.NIH.GOV>
Subject: MLR final edits to BRAIN DRug pricing

See attached MLR edits to BRAIN Drug Pricing. Thanks everyone for their expert input. The doc references the letter to HHS from Doggett and the response as attached. I found them on the internet and attach them here

Sent from my iPhone

Congreſs of the United States
Washington, DC 20515

Secretary Sylvia Mathews Burwell
The U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Director Francis S. Collins
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Secretary Burwell and Director Collins,

We respectfully urge you to utilize your existing statutory authority to respond to the soaring cost of pharmaceuticals. Under certain circumstances, when taxpayer-funded federal research results in a new drug patent, NIH may require the patent holder to license the federally-funded intellectual property to third parties.

In 1980, the Bayh-Dole Act authorized federal agencies that fund private research to retain certain rights in patented inventions, including to assert "march-in rights," under 35 U.S.C. § 203(a)(2), when "action is necessary to alleviate health and safety needs which are not being reasonably satisfied" or, as noted in 35 U.S.C. § 201(f), when the benefits of the patented product are not "available to the public on reasonable terms."

Since NIH has not previously offered official guidance regarding the situations in which march-in rights would apply, we believe that reasonable guidelines can discourage drug price gouging. We urge NIH to issue guidelines to accomplish this goal.

While NIH has appropriately referred to march-in rights as an "extraordinary remedy," too many families and providers are facing an extraordinary challenge from unreasonably priced pharmaceuticals. In short, too many drugs are not "available to the public on reasonable terms."

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High prescription drug prices are not limited to one type of treatment or one type of disease. For example, the rapidly rising costs of specialty drugs, like those to treat cancer, which are frequently developed with taxpayer funds, are keeping those in need from being able to access care. A recent report found that in 2013, the average annual price of specialty prescription drugs was 18 times higher than the average annual price for brand name prescription drugs, and 189 times higher than the average annual price of generic prescription drugs. By 2020, specialty drugs will account for only about 2% of prescriptions, but an estimated 30% of drug spending. Over time, these rising prices could result in higher taxes and/or cuts to public programs like Medicare and Medicaid, which are already spending $140 billion on prescription drugs annually.

We are confident reasonable guidance can be put in place to address price gouging while ensuring that march-in rights are exercised with transparency and fairness. We want pharmaceutical manufacturers to have the certainty of clear guidelines that indicate when march-in rights apply. Because these rights would only be used when wrongdoing occurs, innovation should not be threatened. Establishing strong guidelines protects consumers while reducing the need for having to actually exercise "march-in" rights. With adequate guidance, pharmaceutical companies should be able to make better-informed pricing decisions.

When declining to exercise these march-in rights in response to previous petitions, NIH has suggested that controlling drug costs is a legislative duty. While that is accurate, Congress legislated long ago on a bipartisan basis in delegating authority to federal agencies such as NIH the responsibility to address one aspect of this problem. We call upon you to do that job. The failure to act in the past has undoubtedly sent an unfortunate signal that prices for federally-funded inventions can be set as high as a sick or dying consumer will pay. In 2013, for example, NIH rejected a request to issue rules related to pricing disparities between the United States and other high-income countries. While this may not be the sole standard considered, it exemplifies the type of standard which could be set.

While some experts estimate that about one-quarter of priority-reviewed drugs—drugs deemed especially important by the FDA—could be impacted by NIH fully exercising its march-in rights, we believe that just the announcement of reasonable guidelines in response to price gouging would positively influence pricing across the pharmaceutical industry. The decision how to best use that conduit is appropriately addressed through your prompt action. Just beginning that process will have at least a modest salutary impact on this troubling healthcare problem.

We look forward to prompt response in bringing relief for struggling patients and families.

Sincerely,

Lloyd Doggett

Peter Welch

Jan Schakowsky

John Conyers Jr.

Rosa L. DeLauro

Elijah E. Cummings

Jim McDermott

Barbara Lee

John Lewis

Earl Blumenauer

José E. Serrano

Grace F Napolitano

Bobby Scott

Alcee L. Hastings

Keith Ellison

Yvette D Clarke

Judy Chu

Steve Cohen

Janice Hahn

Matthew A Cartwright

Marcy Kaptur

KY-3

John Garamendi, CA3

Lucille Roybal-Allard

Beto O'Rourke

Louise Slaughter

Chaka Fattah

Karen Bass

Emanuel Cleaver

Raúl M. Grijalva

Jerrold Nadler

Sam Farr

Richard M. Nolan

Brenda L. Lawrence

Mark

Michelle Lujan Grisham

Mark DeSaulnier

Maxine Waters

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAR 0 2 2016

The Honorable Lloyd Doggett
U.S. House of Representatives
Washington, DC 20515

Dear Representative Doggett:

Thank you for your letter concerning the development of guidelines on the use of the Bayh-Dole Act march-in authority. I share your concern about the impact rising drugs costs are having on American patients and their families, as does this Administration.

The Department of Health and Human Services has taken action on the topic of the rising cost of drugs, including a notice to all 50 state Medicaid directors and letters to the CEOs of several drug manufacturers about providing access to therapy for Hepatitis C patients; convening a forum with stakeholders to discuss opportunities to improve patient access to affordable prescription drugs; driving innovation through the President's Precision Medicine Initiative; incorporating value-based and outcomes-based models into purchasing programs in both the public and private sectors; and publishing the Medicare Drug Spending Dashboard to provide information on the most expensive drugs in Medicare Part B and Part D. The FY 2017 President's Budget builds on this work with a number of proposals to improve the access and value Americans get from their medications, without discouraging important and lifesaving innovations.

As you are aware, some drugs utilize patented inventions that were supported by United States Government funding, such as NIH grants. The Bayh-Dole Act lays out the responsibilities of recipients of research grant and contract funding for inventions the institutions make under these awards. The Act, under certain specific circumstances, provides the government with the march-in authority (35 U.S.C. §203) - to ensure that a government-funded invention that covers a drug does not block it from entering the market.

As you mentioned, the government's march-in right allows the funding agency, on its own initiative or at the request of a third party, to grant additional licenses to other responsible applicants. This right is strictly limited and can only be exercised if the agency conducts an investigation and determines that specific criteria are met, such as alleviating health or safety needs or when effective steps are not being taken to achieve practical application of the inventions.

The NIH considered using its march-in authority to address drug pricing concerns in 2004 for Norvir® (ritonavir)[1] and Xalatan® (latanoprost),[2] and in 2013 for the pricing of Norvir® a second time.[3] Links to NIH's reviews and determinations are provided below. In each review, the NIH considered whether the marketed drug met the statutory requirements to justify use of the march-in authority and determined that it did not.

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[1] www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf.

[2] www.ott.nih.gov/sites/default/files/documents/policy/March-in-xalatan.pdf.

[3] www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf.

NIH considers the application of the march-in statute on a case-by-case basis, and is prepared to use its authority if presented with a case where the statutory criteria are met regarding the commercialization and use of an NIH-funded, patented invention, and where march-in could in fact alleviate health or safety needs or address a situation where effective steps are not being taken to achieve practical application of the inventions. After consulting with the NIH, we believe the statutory criteria are sufficiently clear and additional guidance is not needed.

Thank you again for your leadership on this important issue. I look forward to working with you as part of our broader efforts to ensure patients have timely access to innovative, quality, and affordable medications.

If you have further questions, please contact Jim Esquea, Assistant Secretary for Legislation, at (202) 690-7627. I am also sending this response to the co-signers of the letter.

Sincerely,

SMB

Sylvia M. Burwell

b5

b5

b5

b5

b5

b5

From:	Mascola, John (NIH/VRC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F78B40A596B4CA4A2850A429D1AE3F2-JMASCOLA]
Sent:	9/12/2017 6:08:43 PM
To:	Billet, Courtney (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7605eeb349ac41138b32fe3978e3986d-billetc]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]
CC:	Eisinger, Robert (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bad2a8c45514ee48985880de66674ad-eisinger]; Stover, Kathy (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c82722674ba14c2f969bd50dfa6a7af4-stoverk]; Haskins, Melinda (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545e01141619453bb4fc1dcde6c45887-haskinsm]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Paules, Catharine (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e3435aa00e54d419df3e535016c19fa-paulesci]
Subject:	RE: FINAL -- talking points

Thanks, look good. Not an easy task to so quickly handle various comments!

From: Billet, Courtney (NIH/NIAID) [E]
Sent: Tuesday, September 12, 2017 1:15 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Paules, Catharine (NIH/NIAID) [E] <catharine.paules@nih.gov>
Subject: FINAL -- talking points

This is the final version of the talking points that I sent forward, reconciling all edits. In the interest of time, **b5**

b5

Thanks to all for the review and all the helpful (and fast!) comments.

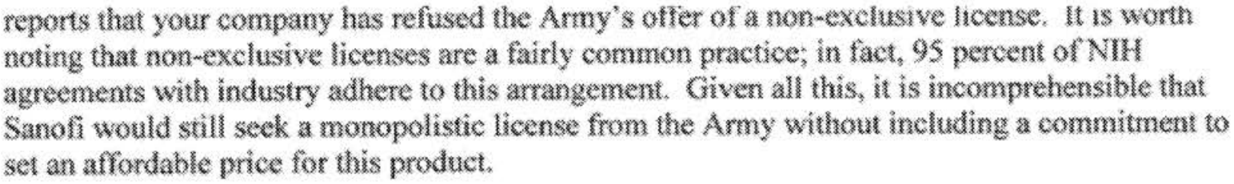
From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, September 12, 2017 11:42 AM
To: Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Paules, Catharine (NIH/NIAID) [E] <catharine.paules@nih.gov>
Subject: RE: Zika vax -- talking pts and website language

b5

From: Marston, Hilary (NIH/NIAID) [E]
Sent: Tuesday, September 12, 2017 11:12 AM
To: Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Paules, Catharine (NIH/NIAID) [E] <catharine.paules@nih.gov>
Subject: RE: Zika vax -- talking pts and website language

b5

b5 KEI and others have used this "most non-exclusive" point to argue against exclusive licenses (see excerpt below from https://www.keionline.org/sites/default/files/Senate-Letter-to-Sanofi-re-Zika-Vaccine-Army-Pricing.pdf). Is the 95% correct? And what does that 95% actually represent (e.g., licenses to techniques, reagents, etc.). Again – not needed for today, but possibly important for interviews.



reports that your company has refused the Army's offer of a non-exclusive license. It is worth noting that non-exclusive licenses are a fairly common practice; in fact, 95 percent of NIH agreements with industry adhere to this arrangement. Given all this, it is incomprehensible that Sanofi would still seek a monopolistic license from the Army without including a commitment to set an affordable price for this product.

From: Mascola, John (NIH/VRC) [E]
Sent: Tuesday, September 12, 2017 10:57 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: Zika vax -- talking pts and website language

Want to highlight Mark's comment on following text:

b5

Mark's comment: b5

b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, September 12, 2017 10:37 AM
To: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>; Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: Zika vax -- talking pts and website language

I have a few comments on the Talking Points. THx

From: Mowatt, Michael (NIH/NIAID) [E]
Sent: Tuesday, September 12, 2017 10:07 AM
To: Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>; Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>
Subject: RE: Zika vax -- talking pts and website language

Proposed changes tracked and highlighted in yellow.

b5 See my comment.

b5

From: Billet, Courtney (NIH/NIAID) [E]
Sent: Tuesday, September 12, 2017 9:54 AM
To: Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: Zika vax -- talking pts and website language

Ok, thanks

From: Mascola, John (NIH/VRC) [E]
Sent: Tuesday, September 12, 2017 9:53 AM
To: Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: Zika vax -- talking pts and website language

b5

From: Billet, Courtney (NIH/NIAID) [E]
Sent: Tuesday, September 12, 2017 9:13 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: FW: Zika vax -- talking pts and website language

HI all -- Edits from HHS on both documents. Would appreciate your review and response. Hope to send ASF a final for one last review by noon. Thanks

From: Wojtowicz, Emma (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=45C6610ACA6E44A08D497630425E5ECD-WOJTOWICZEM]
Sent: 3/22/2018 12:57:53 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Hammersla, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87fb28aa23744c0b855ef0683ac2e8b4-hammerslaa]; Bulls, Michelle G. (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b366f1a4382d44c1bde626e7730c3dd4-bullsmg]; Jackson, Stephanie (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=813a0dc9ddbc4fa2be8ca6ea23d081ca-jacksonsg]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]
Subject: RE: question from a journalist

Thanks, Mark. Would it be OER and/or OMA?

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, March 21, 2018 7:48 PM
To: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Cc: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>; Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Jackson, Stephanie (NIH/OD) [C] <stephanie.jackson3@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Subject: Re: question from a journalist

Not OTT

Sent from my iPhone

On Mar 21, 2018, at 5:02 PM, Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov> wrote:

> Hi Ann-
>
> Quick question, what NIH office would be response for reviewing NIH's support? Is it OTT, or would OER and/or OMA get involved?
>
> Thank you-
> Emma
>
> **From:** Wojtowicz, Emma (NIH/OD) [E]
> **Sent:** Wednesday, March 21, 2018 2:29 PM
> **To:** Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>; Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
> **Cc:** Jackson, Stephanie (NIH/OD) [C] <stephanie.jackson3@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
> **Subject:** RE: question from a journalist
>
> Thanks, Ann!

From: Hammersla, Ann (NIH/OD) [E]
Sent: Wednesday, March 21, 2018 2:28 PM
To: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Jackson, Stephanie (NIH/OD) [C] <stephanie.jackson3@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Subject: RE: question from a journalist

All: OER's statement is:

NIH received Knowledge Ecology International's letter and supporting information on March 19, 2017 and is reviewing NIH's support, if any, in the development of Juxtapid. While NIH does not comment on the details of specific cases while under review, if NIH determines non-compliance issue(s) exist, it will take actions necessary to have the non-compliance corrected to preserve NIH and the government's rights and interests.

Ann

From: Wojtowicz, Emma (NIH/OD) [E]
Sent: Wednesday, March 21, 2018 12:58 PM
To: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Jackson, Stephanie (NIH/OD) [C] <stephanie.jackson3@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Subject: RE: question from a journalist

Thanks, Michelle. I will wait for the updated statement from Ann.

From: Bulls, Michelle G. (NIH/OD) [E]
Sent: Wednesday, March 21, 2018 12:57 PM
To: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Jackson, Stephanie (NIH/OD) [C] <stephanie.jackson3@nih.gov>; Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Subject: RE: question from a journalist

Hi Emma,
Ann will be revising the OER/OPERA statement to add a sentence. Hold tight until she sends it to you.
Please note—the revised statement that you will receive has been approved by Mike Lauer OER DDER.

Thanks!

From: Wojtowicz, Emma (NIH/OD) [E]
Sent: Wednesday, March 21, 2018 11:29 AM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Jackson, Stephanie (NIH/OD) [C] <stephanie.jackson3@nih.gov>
Subject: RE: question from a journalist

Thanks, Ann. **b5**

From: Hammersla, Ann (NIH/OD) [E]
Sent: Wednesday, March 21, 2018 11:26 AM
To: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Jackson, Stephanie (NIH/OD) [C] <stephanie.jackson3@nih.gov>
Subject: FW: question from a journalist

Dear Emma:

The following is the response approved by OPERA.

b5

Ann

From: Wojtowicz, Emma (NIH/OD) [E]
Sent: Tuesday, March 20, 2018 4:24 PM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Subject: RE: question from a journalist

Hi Ann-

I am following up on your email below. Do you have the two-sentence response?

Thanks again for your help!
Emma

From: Hammersla, Ann (NIH/OD) [E]
Sent: Tuesday, March 20, 2018 11:36 AM
To: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Subject: RE: question from a journalist

All:

I drafted a 2-sentence this morning and when I receive an OK to send I will. My draft response included b5

Ann

From: Wojtowicz, Emma (NIH/OD) [E]
Sent: Tuesday, March 20, 2018 11:32 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Subject: RE: question from a journalist

Thanks, Mark. Ann, do you have any input? Thanks!

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, March 20, 2018 10:20 AM
To: Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Cc: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Subject: Re: question from a journalist

Unless you have heard otherwise from Ann, I suggest the previous responses you have used

Sent from my iPhone

On Mar 20, 2018, at 8:46 AM, Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov> wrote:

My apologies, I should have specified that Ed's deadline is 10am. Thanks-

From: Wojtowicz, Emma (NIH/OD) [E]
Sent: Tuesday, March 20, 2018 8:31 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Cc: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Subject: FW: question from a journalist

Hi Mark and Ann

We received an inquiry from Ed Silverman with STAT regarding UPenn transferring patent rights to Aegerion Pharmaceuticals without disclosing that they had received NIH funding, please see the email below. Ed asked a similar question regarding UPenn and CAR T technologies in October. Initially, we provided the following response:

b5

Please advise how we should respond.

Thank you-
Emma

From: Silverman, Ed [mailto:ed.silverman@statnews.com]
Sent: Monday, March 19, 2018 5:29 PM
To: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: question from a journalist

Hi Guys,

An advocacy group, KEI, wrote a letter to Karen Rogers and Jill Roering saying that six patents for a cholesterol treatment held by Aegerion Pharmaceuticals were discovered by a UPenn researcher, but the school - which later transferred the rights to the company - never disclosed NIH grant funding.

The letter is attached and here is a supporting memo...

https://www.keionline.org/wp-content/uploads/2018/03/Juxtapid-Failure2disclose-Daniel-Rader-19Mar2018.pdf

KEI says the government has the right to take title and should do so, since failing to disclose the funding violates federal law and regulations.

Wondering what NIH will do. Any comment?

I"m writing about this in the morning.

Thanks
ed silverman
STAT News / Pharmalot
973-493-7851

www.statnews.com/pharmalot/

From: BioHealth Innovation [bhi@biohealthinnovation.org]
Sent: 5/23/2018 10:43:19 AM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: BioHealth Innovation News

BioHealth Innovation

If you are having trouble viewing this email, please click here

May 23, 2018

BioHealth Innovation Appoints Jarrod Borkat as new Vice Chairman of the Board

MedImmune Sr. Director, Partnering & Strategy filling role previously held by Emergent BioSolutions CEO, Daniel J. Abdun-Nabi

BioHealth Innovation, Inc. (BHI) announced that its Board of Directors has unanimously approved the appointment of MedImmune Sr. Director, Partnering & Strategy, Jarrod Borkat as new Vice Chairman. MedImmune, the global biologics research and development arm of AstraZeneca, is a Founding Partner of BHI and continues to be a leader in building the BioHealth Capital Region. BHI would like to thank Emergent BioSolutions CEO, Daniel J. Abdun-Nabi, for his service as Vice Chairman. He will remain as a member of the Board of Directors. Mr. Abdun-Nabi also previously served as chairman of the Maryland Life Sciences Advisory Board (LSAB) and currently serves on Maryland Governor Larry Hogan's Excel Board.

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Margaret Anderson, Managing Director at Deloitte Consulting LLP, sits down with host Rich Bendis for this episode of BioTalk. They discuss her career path, putting patients at the center of biomedical and public health, and engaging with all sectors

Margaret Anderson, Managing Director at Deloitte Consulting LLP, sits down with host Rich Bendis for this episode of BioTalk. They discuss her career path, putting patients at the center of biomedical and public health, and engaging with all sectors. Margaret Anderson is a Managing Director at Deloitte Consulting LLP focused on using strategy to make organizations, agencies, and programs stronger and more laser focused on outcomes for patients. Her career has traversed biomedical and public health policy and she's motivated by the change she's seen in bringing treatments and solutions for patients forward.

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Kite Pharma Announces New Worldwide Facilities Including Expanded Collaboration with National Cancer Institute to Support Cell Therapy Pipeline in new 26K sf facility in Gaithersburg, MD

Kite, a Gilead Company (Nasdaq: GILD), today announced it has leased a new facility in the Netherlands to engineer cell therapies in Europe. The 117,000 square-foot site in Hoofddorp (SEGRO Park Amsterdam Airport) will enable Kite to efficiently manufacture and deliver its cell therapies to people living with cancer in Europe and will provide more than 300 new jobs when fully operational in 2020.

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175,000 sq. ft. Development in Bethesda Will Focus on Creating "Bethesda Bio" — MCEDC

StonebridgeCarras and The Donohoe Companies announced plans today for their project at 8280 Wisconsin Avenue which will focus its 175,000 square feet of commercial space on bringing life sciences to the Bethesda Central Business District (CBD). StonebridgeCarras and Donohoe's vision for the project is to capitalize on two converging trends: employers locating their offices in live, work and play environments with access to mass transportation; and life sciences companies co-locating near thought leaders and institutions driving research and advancement.

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Marketing Communications Internship Opening at BHI

BioHealth Innovation, Inc. (BHI) is a nonprofit organization focused on supporting BioHealth entrepreneurs and related industry growth in Montgomery County and the BioHealth Capital Region (Maryland, D.C. and Virginia). BHI is seeking an energetic and motivated Marketing Intern to assist with communications and marketing-related projects. This position is estimated to be 15-25 hours per week, would start immediately, and continue for 12 weeks. In addition to the responsibilities listed below, the intern may attend meetings and programs to understand the full work of BHI and how the organization accomplishes its mission through constituent outreach and support, commercialization and partnership activity.

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Iowa AgriTech Accelerator announces startups for program's 2018 cohort - VakSea accepted to participate

The Iowa AgriTech Accelerator is a mentor-led accelerator focused on AgTech innovations. The Accelerator is led by innovators and leaders in several areas of agriculture, and seeks startups ready to change the status quo.

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MockV Solutions Announces Collaboration with NIH for Predicting Viral Clearance During Small Scale Bioprocess Development – MockV Solutions

MockV Solutions, Inc. (MockV or the Company), a company developing innovative products to analyze virus clearance during process development, announced today that it will be collaborating with the Vaccine Production Program of the Vaccine Research Center/National Institute of Allergy and Infectious Diseases/National Institutes of Health (VRC, NIAID, NIH) to evaluate its lead product candidate, the MVM-MVP Kit. The MVM-MVP Kit contains a non-infectious "Mock Virus Particle" (MVP) spiking surrogate that mimics the physicochemical characteristics of Minute Virus of Mice (MVM), a small and physiochemically resistant parvovirus, used as a universal standard for assessing viral clearance during process validation studies. The intention of this collaboration is to determine if the non-infectious MVP could be used as an accurate and economic indicator of MVM clearance during small scale bioprocess development studies.

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Maryland Tech Council Announces Winners of 30th Annual Industry Awards | Business Wire

The Maryland Tech Council (MTC), Maryland's largest technology trade association, announced the winners of its 30th Annual Industry Awards during a celebration and ceremony at The Hotel at the University of Maryland attended by more than 550 business leaders from around the state.

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Johns Hopkins startup gets funding from company turning research into businesses - Technical.ly Baltimore

A company that works to turn intellectual property into businesses is backing a new Johns Hopkins startup developing therapeutics to treat cancer.

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Rexahn Phase 2a Combination Study of RX-3117 and Abraxane® in First-line Metastatic Pancreatic Cancer Patients Advances to Second Stage (NYSE:RNN)

Rexahn Pharmaceuticals, Inc. (NYSE American:RNN), a clinical-stage biopharmaceutical company developing innovative, targeted therapeutics for the treatment of cancer, advances its ongoing Phase 2a study of RX-3117 in combination with Abraxane® in first-line patients with metastatic pancreatic cancer following a recently completed routine Safety Monitoring Committee (SMC) review.

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MdBio Foundation Names Laurel 12th Grader Katy Wnuk-Fink as Maryland BioGENEius Finalist - Business Wire

The MdBio Foundation, a non-profit that provides STEM education and workforce development to underserved communities, today announced that Katy Wnuk-Fink – a senior from Laurel who attends Reservoir High School – was named winner of the 2018 Maryland BioGENEius Challenge, the premier competition for high school students that recognizes outstanding original research in biotechnology for healthcare, sustainability, and the environment. As the Maryland BioGENEius finalist, Wnuk-Fink will represent the state in the International BioGENEius Challenge at the BIO International Convention in Boston in June.

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TEDCO awards $7.1 million to 25 stem cell projects in Maryland - Baltimore Business Journal

Maryland Technology Development Corp. has doled out $7.1 million to 25 companies and researchers working on stem cell products and medical therapies.

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Protenus Recognized as One of the Best Places to Work in Healthcare in 2018 - Protenus

Protenus has been selected by Modern Healthcare as one of the 2018 Best Places to Work in Healthcare. The complete list of this year's winners, in alphabetical order, is available here. Modern Healthcare will publish a special supplement featuring ranked lists of all the winners along with the October 1 issue.

Read More

Paragon Bioservices Recognized as Life Science Company of the Year by Maryland Tech Council - Paragon Bioservices, Inc.

Paragon Bioservices, Inc. (Paragon), the leading private equity-backed biologics contract development and manufacturing organization (CDMO) with proven expertise in gene therapy and next-generation vaccines, was named the 2018 Life Science Company of the Year by the Maryland Tech Council (MTC). The announcement came at MTC's 30th Annual Industry Awards held last night in the Hotel at the University of Maryland in College Park.

Read More

Grand Prize Winner for the Innovation for Impact Prize Announced by SoBran and the Maryland Tech Council

SoBran BioScience, a division of SoBran Inc, and a leading provider of pre-clinical GLP contract research announced the grand prize winner of the Innovation for Impact Prize sponsored in partnership with the Maryland Tech Council (MTC). This Grand Prize was awarded last night at the MTC 30th Anniversary Industry Awards Celebration.

Read More

KEI Sues NIH Over Gilead CAR-T Patents - PharmaLive

A nonprofit organization, Knowledge Ecology International (KEI), recently filed a lawsuit against the National Institutes of Health (NIH) over Gilead Sciences' patents for a new chimeric antigen receptor T-cell (CAR-T) therapy.

KEI calls itself a “not for profit non government organization that searches for better outcomes, including new solutions, to the management of knowledge resources. KEI is focused on social justice, particularly for the most vulnerable populations, including low-income persons and marginalized groups.”

Read More

SBA Seeks Grant Applications from Organizations - Hudson Valley News Network

The U.S. Small Business Administration, under its Federal and State Technology (FAST) Partnership Program, is soliciting grant applications from New York organizations to help boost the development of technology from small businesses.

Read More

Nostopharma LLC is working on a cure for a common surgery complication - Washington Business Journal

A complication from surgery can cost tens of thousands of dollars and require more surgery to correct — but a young Maryland startup is cooking up a more affordable and less invasive solution.

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NIST Revises Intellectual Property Rights - Federal Labs

Join the FLC on Tuesday, May 22 at 1:00 p.m. EDT for an inside look into these new regulations with NIST's Courtney Silverthorn. To register for this webinar, visit http://connect.federallabs.org/new-t2-regulations-what-you-need-to-know.

Read More

RFA-HL-19-018: NHLBI SBIR Phase IIB Small Market Awards to Accelerate the Commercialization of Technologies for Heart, Lung, Blood, and Sleep Disorders and Diseases (R44 Clinical Trial Optional)

The Small Business Innovation Research (SBIR) Program is an important National Institutes of Health (NIH) funding mechanism used to develop innovative solutions that address public health challenges. A major objective of the SBIR Program is to facilitate the commercialization of technologies developed by small business concerns (SBCs). Yet, the development of biomedical products is often impeded by a significant funding gap between the end of the SBIR Phase II award and the commercialization stage. This gap is increased by the barriers associated with technologies under development for small commercial markets, such as those focused on rare diseases or young pediatric populations. This Funding Opportunity Announcement (FOA) invites small businesses to submit SBIR grant applications to support later stage research and development (referred to as Phase IIB) for promising projects that were previously funded by SBIR or STTR (Small Business Technology Transfer) Phase II awards that address rare diseases or young pediatric populations (aged 0-12 years and defined in Section IV, part 7), and will require eventual Federal regulatory approval/clearance. The goal of this FOA and the resulting Phase IIB awards is to assist applicants in pursuing the next appropriate milestone(s) necessary to advance a product to regulatory approval and commercialization by promoting partnerships between small business awardees and third-party investors and/or strategic partners, including patient advocacy organizations.

Read More

RFA-HL-19-017: NHLBI SBIR Phase IIB Bridge Awards to Accelerate the Commercialization of Technologies for Heart, Lung, Blood, and Sleep Disorders and Diseases (R44 - Clinical Trial Optional)

The Small Business Innovation Research (SBIR) Program is an important funding mechanism that the National Institutes of Health (NIH) uses to develop innovative solutions that address public health challenges. A major objective of the SBIR Program is to facilitate the commercialization of technologies developed by small business concerns (SBCs). Yet, the development of biomedical products is often impeded by a significant funding gap between the end of the SBIR Phase II award and the commercialization stage. This Funding Opportunity Announcement (FOA) invites SBIR grant applications from SBCs to support later stage research and development (referred to as Phase IIB) for promising projects that were previously funded by SBIR or STTR Phase II awards and will require eventual Federal regulatory approval/clearance. The goal of this FOA and the resulting Phase IIB awards is to assist applicants in pursuing the milestone(s) necessary to advance a product to regulatory approval and commercialization by promoting partnerships between SBIR Phase II awardees and third-party investors and/or strategic partners.

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Top 5 Trends in the Pharmaceutical Industry in 2018

This white paper takes an in depth look at trends in the pharmaceutical industry that are anticipated to make a significant impact on the sector in 2018. Industry professionals can leverage this information to make the course adjustments that will give their companies a competitive edge in the market.

Read More

Medical Fish Skin Company Kerecis Receives the Industry Award for Entrepreneurship from the President of Iceland

Today the President of Iceland awarded Kerecis the Industry Award for Entrepreneurship. Kerecis is the creator, manufacturer and patent holder of revolutionary, fish-skin-based therapeutic products that speed up the healing process of human wounds and repair tissue damage.

Read More

Pace of exits picks up for venture development organizations in Q1 - SSTI

Venture development organizations (VDO), nonprofit organizations across the country investing in innovation startups to help grow their regional economies as well as earn a respectable return, saw at least 20 exits in the first quarter of 2018, based on data entered on Pitchbook.com. Here are some examples from the quarter:

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Mount Sinai's Icahn medical school launches $10 million investment fund | Crain's New York Business

The Icahn School of Medicine at Mount Sinai has created a $10 million accelerator fund to speed up the commercialization of research at the school. It's starting with two investments in drug-development ventures.

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Raising your next round? Six qualities that define top healthcare VCs - MedCity News

Founders can become myopic during the long, stressful process of fundraising. Many focus solely on the amount of money they're going to raise, their valuation, and the brand name of the investors they are pitching.

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A look inside Tufts, Biolabs new biotech incubator Launchpad in downtown Boston - Boston Business Journal

Tufts University has joined the biotech incubator craze, launching a coworking space in Boston earlier this year that organizers hope will foster another life sciences cluster in the heart of the city.

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Boston Children's, Red Hat develop cloud platform for images | Health Data Management

Boston Children's Hospital has teamed up with open-source solution provider Red Hat to create a web-based medical image platform that will speed the time it takes to share and analyze life-saving images.

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AZBio initiative aims to cure funding gap that ails Arizona

Trying to build on Arizona's significant investments in the life science discovery and healthcare delivery infrastructure, the state's leaders are focused on bridging the funding gap that slows the growth of Arizona-based life science companies. Leaders of Arizona's life science sector share a drive to accomplish a common goal: accelerate the growth of local companies that are developing and delivering innovative treatments that truly change lives.

Read More

IPO Slowdown Leads Silicon Valley Venture Giant NEA to Sell $1 Billion Worth of Startup Stakes - WSJ

New Enterprise Associates, one of Silicon Valley's largest venture-capital firms, plans to sell off a big chunk of its startup investments in response to a dearth of initial public offerings, according to people familiar with the discussions.

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From: Allen-Gifford, Patrice (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=67262490D6D441B48EFEC1AFF0700250-ALLENGIFFOR]
Sent: 8/7/2018 9:49:16 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Gale, Jamie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c7c93b348c44d9a824ced1ecd6b9ae6-galejr]
Subject: FW: Request for Call Regarding May 18th Letter on Non-disclosure of NIH Funding of Vizamyl Patents
Attachments: Azar-KEI-CoverLetter-Vizamyl-patents-18May2018.pdf; Vizamyl-patent-memo-UofPittsburgh-Klunk-Mathis-Wang-18May2018.pdf; KEI-Briefing-Note-2018-1.pdf

Hi Mark, I don't see you copied on this email from today, but Ann may have shared it with you. Do you have any thoughts about assigning this request for a phone call? OER? OSP? Note that the Department sent the letter to Secretary Azar (first attachment) to NIH as an FYI (no action).

Thanks for your advice.

patrice

From: Claire Cassedy <claire.cassedy@keionline.org>
Sent: Tuesday, August 07, 2018 2:16 PM
To: NIH OTT (NIH/OD) <NIHOTT@mail.nih.gov>; secretary@hhs.gov; Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>; Levinson, Dan R (OIG/IO) <dan.levinson@oig.hhs.gov>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Cc: James Love <james.love@keionline.org>; Merith Basey <merith@essentialmedicine.org>; Luis Gil Abinader <luis.gil.abinader@keionline.org>
Subject: Request for Call Regarding May 18th Letter on Non-disclosure of NIH Funding of Vizamyl Patents

To Whom It May Concern:

On May 18, 2018 KEI requested that the Department of Health and Human Services (HHS) investigate the failure to disclose National Institutes of Health (NIH) funding in four patents on Vizamyl (INN flutemetamol F 18), which is used to evaluate possible cases of Alzheimer's disease and other causes of cognitive decline. Attached is a copy of the request and related attachments.

The patents in question are assigned to the University of Pittsburgh, and all list the same three inventors, William Klunk, Chester A. Mathis, Jr., and Yanming Wang. As the request details, in published papers that describe the inventions in Vizamyl, the inventors/authors acknowledge NIH and Department of Energy (DOE) funding of their work, but did not report the grants on the patents themselves, and the patents do not appear in the NIH RePORTER database.

KEI has asked HHS, as a remedy to this failure to disclose federal funding, to take title to the patents (a remedy available to the government in cases of non-disclosure of federal funding, as laid out in the Bayh-Dole Act).

We would like to request a phone call to discuss this outstanding request to investigate. Please let us know who the appropriate contact would be on this issue and what dates/times they would be available for a call. Thank you in advance for your time and attention to this issue.

Sincerely,
Claire Cassedy

--
Claire Cassedy

Knowledge Ecology International
1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
Tel.: 1.202.332.2670

On Fri, May 18, 2018 at 1:07 PM, James Love <james.love@keionline.org> wrote:

> Attached is a coverletter, memo and attachment concerning the failure of the University of Pittsburgh to disclose NIH funding in 4 patented inventions on the drug Vizamyl.
>
> James Love
>
> --
>
> James Love. Knowledge Ecology International
> http://www.keionline.org/donate.html
> KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, twitter.com/jamie_love

---

From: Petrik, Amy (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C4EC05A179F04067B61F20605E911E7C-PETRIKA]
Sent: 11/9/2017 8:22:57 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]; Stover, Kathy (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c82722674ba14c2f969bd50dfa6a7af4-stoverk]
CC: Salata, Carol (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f98ca6a1f9fc4cfdbbf4036ca8cbace4-csalata]; Feliccia, Vincent (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f3a54860cb941c1abe1df786e478e00-vfeliccia]; Frisbie, Suzanne (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c402740ceaad4d4f97a8c28f16fbb349-frisbies]
Subject: RE: Proposed grant of an exclusive license to Zika Vaccine
Attachments: Response to KTreanor DRAFT 171106_AFP.docx

Hi Mike,

Taking Mark's suggestion into account, I've made a few edits to Kathy's draft message.

If anyone has suggestions, please let me know.

I've been receiving phone calls from KEI today so I'd like to get something out soon.

Best,
Amy

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, November 06, 2017 5:17 PM
To: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>
Cc: Salata, Carol (NIH/NIAID) [E] <csalata@niaid.nih.gov>; Feliccia, Vincent (NIH/NIAID) [E] <vfeliccia@niaid.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>; Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>
Subject: RE: Proposed grant of an exclusive license to Zika Vaccine

b5

Thx for sharing.

From: Mowatt, Michael (NIH/NIAID) [E]
Sent: Monday, November 06, 2017 4:57 PM
To: Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Salata, Carol (NIH/NIAID) [E] <csalata@niaid.nih.gov>; Feliccia, Vincent (NIH/NIAID) [E] <vfeliccia@niaid.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>
Subject: RE: Proposed grant of an exclusive license to Zika Vaccine

See proposed draft (attached).

From: Stover, Kathy (NIH/NIAID) [E]
Sent: Friday, November 3, 2017 10:35 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>
Cc: Salata, Carol (NIH/NIAID) [E] <csalata@niaid.nih.gov>; Feliccia, Vincent (NIH/NIAID) [E] <vfeliccia@niaid.nih.gov>; Greco, Natalie (NIH/NIAID) [C] <natalie.greco@nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>
Subject: RE: Proposed grant of an exclusive license to Zika Vaccine

Hi all,
In talking it over here at NIAID OCGR, we think b5

b5

Best,
Kathy

Kathy Stover
Branch Chief
News and Science Writing Branch
National Institute of Allergy and Infectious Diseases (NIAID)
Office of Communications and Government Relations
National Institutes of Health/HHS
31 Center Drive, Room 7A17E
Bethesda, MD 20892
Phone: (301) 496-8864
E-mail: kstover@nih.gov
NIAID Media Line: (301) 402-1663

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Friday, November 03, 2017 9:59 AM
To: Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>
Cc: Salata, Carol (NIH/NIAID) [E] <csalata@niaid.nih.gov>; Feliccia, Vincent (NIH/NIAID) [E] <vfeliccia@niaid.nih.gov>; Greco, Natalie (NIH/NIAID) [C] <natalie.greco@nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>
Subject: RE: Proposed grant of an exclusive license to Zika Vaccine

b5

From: Petrik, Amy (NIH/NIAID) [E]
Sent: Friday, November 03, 2017 8:31 AM
To: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>
Cc: Salata, Carol (NIH/NIAID) [E] <csalata@niaid.nih.gov>; Feliccia, Vincent (NIH/NIAID) [E] <vfeliccia@niaid.nih.gov>; Greco, Natalie (NIH/NIAID) [C] <natalie.greco@nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: FW: Proposed grant of an exclusive license to Zika Vaccine

Hi Mike,

Below is the message from KEI.

Thanks,
Amy

From: Kim Treanor [mailto:kim.treanor@keionline.org]
Sent: Wednesday, October 25, 2017 2:53 PM
To: Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>
Subject: Proposed grant of an exclusive license to Zika Vaccine

Dear Dr. Petrik,

I am writing in regards to the proposed grant of an exclusive patent license of a DNA-based vaccine for prevention of Zika virus infection to PaxVax Inc, as referenced in 82 FR 47537. As a part of this licensing agreement or separately from it, if the exclusive license is granted, will the NIAID or another division of the NIH also provide PaxVax with grants or financial support to conduct clinical trials on this vaccine candidate? PaxVax reports on their website that they have a Zika vaccine candidate in the pipeline which they are working on with the CDC. Do you know if this vaccine candidate has received any financial support from NIAID or another division of the NIH?

Thank you for your assistance.

Best regards,
Kim

--

Kim Treanor
Knowledge Ecology International
kim.treanor@keionline.org
tel.: +1.202.332.2670

b5

b5

From: Jorgenson, Lyric (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=JORGENSONLA]
Sent: 3/6/2017 4:36:28 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Wolinetz, Carrie (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Wolinetzcdc9a]
CC: Carr, Sarah (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=CARRS]; Volkov, Marina (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=nimh/cn=mvolkov]; Dodson, Sara (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Dodsonse]; Baden, Elizabeth (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Badenem]; Hagedorn, Caroline (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Colemancj]; Fennington, Kelly (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=FENNINGTONKNEW]
Subject: RE: MLR final edits to BRAIN DRug pricing
Attachments: Drug Pricing OSP edits MLR 2_LJ.docx

Hi Mark,

Thanks for sending this along, and thanks to the whole team for consolidating the entry.

I had a few thoughts when reading this:

b5

There are a few other comments/edits in the text for your consideration. I think we should go ahead and move it along – if Carrie gets a chance to read she can pop in!
LJ

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Saturday, March 04, 2017 11:42 AM
To: Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>
Cc: Carr, Sarah (NIH/OD) [E] <CarrS@OD.NIH.GOV>; Volkov, Marina (NIH/OD) [E] <mvolkov@od.nih.gov>; Dodson, Sara (NIH/OD) [E] <sara.dodson@nih.gov>; Baden, Elizabeth (NIH/OD) [E] <badenem@od.nih.gov>; Hagedorn, Caroline (NIH/OD) [E] <caroline.hagedorn@nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <jorgensonla@od.nih.gov>; Fennington, Kelly (NIH/OD) [E] <FenningK@OD.NIH.GOV>
Subject: MLR final edits to BRAIN DRug pricing

See attached MLR edits to BRAIN Drug Pricing. Thanks everyone for their expert input. The doc references the letter to HHS from Doggett and the response as attached. I found them on the internet and attach them here

Sent from my iPhone

b5

b5

b5

b5

b5

b5

b5

From: Greene, Jaime (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E06E39F0BCD34511A92DF20C5DC8722A-GREENEJAIME]
Sent: 6/25/2018 1:43:53 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]
Subject: FW: A-257-2018 response to KEI
Attachments: Morphiex license; a-257-2018_Response to KEI.docx

Dear Mark,
Attached please find a response to KEI for your review.
The PD memo and FR notice can be found in the ELCG folder of Sharepoint:
https://spweb.od.nih.gov/OTT/DTDT/ELCG/Forms/AllItems.aspx?RootFolder=%2FOTT%2FDTDT%2FELCG%2FApril%2025%2C%202018&FolderCTID=0x0120006450990D1683AD4896040FCDE1260FA6&View={844AB5DF-F7A9-4488-BC2E-FC9CB6F6C0E8}

Please let me know if you have any concerns. I'd greatly appreciate a response by COB Wednesday, 6/27.
Thanks,
Jaime

Jaime Meredith Greene, M.S.
Senior Technology Transfer Manager
NCI Technology Transfer Center

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From: James Love [james.love@keionline.org]
Sent: 5/31/2018 3:28:38 PM
To: Greene, Jaime (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e06e39f0bcd34511a92df20c5dc8722a-greenejaime]
Subject: Morphiex license

Dear Jaime Greene,

I believe this mail bounced for some reason yesterday.

Jamie

Jaime M. Greene
Senior Licensing and Patenting Manager
NCI Technology Transfer Center
Email: greenejaime@mail.nih.gov.

Date: May 30, 2018

Re: Prospective Grant of an Exclusive Patent License: Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Hematological Cancers. Notice for comment published in 83 FR 22501.

Dear Jaime Greene:

Knowledge Ecology International (KEI), HealthGap and the Union for Affordable Cancer Treatment (UACT are organizations concerned about drug pricing and access to patented medicines, offering comments on the grant of an exclusive license of the National Institutes of Health (NIH) patents noticed in 83 FR 22501, to Morphiex Biotherapeutics ("Morphiex") located in Boston, MA. The above entities oppose the issuing of the license unless:

A.
B. The NIH has determined that an exclusive license is "a reasonable and necessary incentive" to induce investments for the development and practical application of the invention, as is required by 35 USC § 209, and shares its analysis with the public; and

B.
C. The NIH limits the scope of rights for the exclusivity to only those rights reasonably necessary to induce investments for the development and practical application of the invention, and in particular, that the field of use is sufficiently narrow, that the term of the exclusivity is sufficiently limited, and that the license contains sufficient safeguards to ensure that the invention is "available to the public on reasonable terms," as is required by 35 USC § 209 and 35 USC § 201(f).

Morphiex Biotherapeutics does not appear to have a web page, and there is almost no information available about the company, other than a February 27, 2018 registration of the company in Delaware. As of May 23, 2018, the company Facebook page had only one entry, which was just a logo and no text. One imagines that such a company may also have few assets, yet the NIH is proposing an exclusive license of inventions that have a potential for the treatment, prevention, and diagnosis of hematological cancers.

Our comments address three areas of concern, (1) the pricing, affordability and access issues, (2) freedom for researchers to use the inventions, and (3) requirements for transparency of the development and commercialization of the medicine.

We propose the following safeguards regarding the pricing of and access to products that use the inventions:

1.
2. Products are priced no higher in the United States than the median price charged in the seven largest economies as measured by nominal GNI that have a nominal GNI per capita of at least 50 percent of the United States. To fully appreciate our concerns about the discriminatory pricing that makes US residents pay more than everyone else, please review the cross country price comparisons here: http://drugdatabase.info/drug-prices/
3.
4.
5. Prices for products in the United States do not exceed the estimated value of the treatment, as determined by independent health technology assessments selected by Department of Health and Human Services (HHS).
6.
7.
8. Patient co-payments under third party Medicare and private reimbursement programs are affordable.
9.
10.
11. The geographic area for the exclusivity excludes countries with a per capita income less than 30 percent that of the United States, and, if there is no such exclusion, the company be required to report annually on the reasonable and feasible measures that will be taken to ensure access to patients living in such countries. Here, please note the data from http://drugdatabase.info/drug-prices/, which shows that in many developing countries, prices are frequently higher than the prices for high income countries in Europe, despite the much lower per capita income in developing countries (including for taxpayer funded cancer drugs), illustrating the need for a policy to be included in NIH licenses.
12.
13.
14. The initial period of exclusivity is set at seven years, subject to extensions if the company can demonstrate it has not recovered sufficient profits given the risk-adjusted value of the clinical trials used to register similar drugs for the lead indication.
15.
16.
17. Absent satisfaction of the requirements of proposed safeguard number 5, the exclusivity of the product be reduced when cumulative global revenues for the product exceed $1 billion, by one year for every $0.5 billion in cumulative sales that exceed $1 billion in cumulative sales.

Note that the licensing of inventions to the company significantly reduces the company's costs of preclinical research, which various studies have estimated to be 40 to 55 percent of drug development costs on a risk- and capital cost-adjusted basis.

To address research by third parties on the patented invention, we propose the NIH explicitly permit researchers worldwide to use the inventions for research purposes, regardless of whether or not research has a grant or contract from a U.S. government agency, and for both profit or non-profit organizations.

To address transparency, we proposes the following requirements.

The company will be required to provide an annual report for the public providing disclosures of the following items:

1.
2. The amount of money R&D to obtain FDA and foreign government approvals of the inventions, including in particular, the amount of money spent each year on each trial, and the relevant tax credits, grants and other subsidies received from any government or charity relating to those R&D outlays,
3.
4.
5. The prices and revenue for the products, by country,
6.
7.
8. The number of units sold, in each country,
9.
10.
11. The product-relevant patents obtained in each country, and
12.
13.
14. The regulatory approval obtained in each country.

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,
twitter.com/jamie_love

b5

From: Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]
Sent: 9/11/2017 3:19:20 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Latest version of statement on Salubris

b5

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)

This message is intended for the exclusive use of the recipient(s) named above. It may contain information that is PROTECTED or PRIVILEGED, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, September 11, 2017 10:49 AM
To: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Subject: FW: Latest version of statement on Salubris

Dale:

b5

If it is easier to talk, let me know.

Thanks,
Mark

From: Myles, Renate (NIH/OD) [E]
Sent: Monday, September 11, 2017 10:36 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Cc: Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>
Subject: RE: Latest version of statement on Salubris

This is for public inquiries.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, September 11, 2017 10:34 AM

To: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: Latest version of statement on Salubris

Could you please send me your latest version of the statement you are sending folks who ask about why we plan to give an exclusive license to Salubris for the cancer cell therapy?

NCI has comments from KEI and individuals they received from the FR notice that they need to respond to.

Thanks

Mark L. Rohrbaugh, Ph.D., J.D.
Special Advisor for Technology Transfer
Director, Division of Technology Transfer and Innovation Policy
Office of Science Policy
Office of the Director
National Institutes of Health

From: Kassilke, Deborah (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=KASSILKED]
Sent: 1/18/2017 6:48:12 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: Mark: Question re: FOIA for OTT

To your knowledge b5
b5

From: Kassilke, Deborah (NIH/OD) [E]
Sent: Wednesday, January 18, 2017 1:45 PM
To: Uhl, Katherine (NIH/OD) [V] <katherine.uhl@nih.gov>
Cc: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>; Allen, Marin (NIH/OD) [E] <AllenM1@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: Question re: FOIA for OTT

Thanks you Katherine – and welcome.

b5

Please advise?
Deb

From: Uhl, Katherine (NIH/OD) [V]
Sent: Wednesday, January 18, 2017 1:26 PM
To: Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov>
Cc: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>; Allen, Marin (NIH/OD) [E] <AllenM1@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: Question re: FOIA for OTT

Deb,

Attached are the two response letters that went to KEI in 2016. We have three pending requests from them. I left you a voicemail and I think you are out today. I am available tomorrow until 1pm if you have any further questions.

Katherine
NIH FOIA
301-496-5633

From: Kassilke, Deborah (NIH/OD) [E]
Sent: Wednesday, January 18, 2017 11:43 AM
To: Allen, Marin (NIH/OD) [E] <AllenM1@mail.nih.gov>; Uhl, Katherine (OC) (FDA/OC) <Katherine.Uhl@fda.hhs.gov>; Bartok, Lauren (NIH/NIAID) [E] <lauren.bartok@nih.gov>
Cc: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Burklow, John (NIH/OD) [E] <BurklowJ@OD.NIH.GOV>
Subject: RE: Question re: FOIA for OTT

Hello Marin –

I really need to understand the FOIA responses to KEI's previous requests. I know Susan Cornell was working on them over the summer. Can you advise what has been found?

I feel I need to respond in some fashion to KEI regarding their requests. Please advise, and thank you.
Deb

From: Allen, Marin (NIH/OD) [E]
Sent: Thursday, January 12, 2017 5:44 PM
To: Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov>; Uhl, Katherine (OC) (FDA/OC) <Katherine.Uhl@fda.hhs.gov>; Bartok, Lauren (NIH/NIAID) [E] <lauren.bartok@nih.gov>
Cc: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Burklow, John (NIH/OD) [E] <BurklowJ@OD.NIH.GOV>
Subject: RE: Question re: FOIA for OTT

Hi, Deb

Thanks for the note. Katherine Uhl is on a detail from FDA to help us out. She is the deputy there and joined us on Monday. Lauren Bartok was with us for a long time (and we miss her!). They will be able to see what the history is on KEI. We may have some language already.

Best,

Marin

From: Kassilke, Deborah (NIH/OD) [E]
Sent: Thursday, January 12, 2017 4:53 PM
To: Allen, Marin (NIH/OD) [E] <AllenM1@mail.nih.gov>
Cc: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: Question re: FOIA for OTT

Hello Marin –

How did you end up dealing with FOIAs? Congratulations? Grin.

Before Susan Cornell left, she was working on some OTT related FOIA requests from KEI. We have received 3 requests from them (see the attached). Before we resound I would like to know what Susan may have sent them on previous requests. How do I find out what has been issued previously?

Mark Rohrbaugh was kind enough to speak with them on the phone today and explained that CRADAs do not require a Fed Registry Notice. I'll reference that when I respond to the request from Mr. Love.

Please advise and I appreciate your help.
Deb

Deborah Kassilke
Director, Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852
E-Mail: Deborah.Kassilke@nih.gov
Phone: 301-435-5294

Cell: **b6**

From:	Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]
Sent:	5/18/2018 6:09:10 PM
To:	Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject:	FW: Letter concerning non-disclosure NIH funding of patented inventions on Vizamyl
Attachments:	Azar-KEI-CoverLetter-Vizamyl-patents-18May2018.pdf; Vizamyl-patent-memo-UofPittsburgh-Klunk-Mathis-Wang-18May2018.pdf; KEI-Briefing-Note-2018-1.pdf

From: James Love <james.love@keionline.org>
Sent: Friday, May 18, 2018 1:07 PM
To: secretary@hhs.gov; Claire Cassedy <claire.cassedy@keionline.org>
Cc: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>; Levinson, Dan R (OIG/IO) <dan.levinson@oig.hhs.gov>
Subject: Letter concerning non-disclosure NIH funding of patented inventions on Vizamyl

Attached is a coverletter, memo and attachment concerning the failure of the University of Pittsburgh to disclose NIH funding in 4 patented inventions on the drug Vizamyl.

James Love

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
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KEI
KNOWLEDGE ECOLOGY
INTERNATIONAL

May 18, 2018

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Via email: secretary@hhs.gov

Re: Investigation into the failure disclose NIH funding in inventions patented by the University of Pittsburgh for flutemetamol F 18),

Dear Secretary Azar:

We are writing to ask the Department of Health and Human Services (HHS) to investigate and if applicable, to remedy a failure to disclose National Institutes of Health (NIH) funding in four inventions patented by the University of Pittsburgh. The four inventions are identified in the FDA Orange Book as patents for Vizamyl (INN flutemetamol F 18), used to evaluate possible cases of Alzheimer's disease or other causes of cognitive decline. Access to the tests is currently restricted, including restrictions on reimbursements by Medicare.

Knowledge Ecology International (KEI) asks that HHS take title to the four patents. The legal basis for the proposed remedy is set out in the attached memorandum, *Bayh-Dole Obligations to Disclose Federal Funding in Patented Inventions*.[1] One of the possible remedies for non-disclosures, as set out in 35 U.S.C. § 202(c)(1) and 37 C.F.R. § 401.14, is for the federal government to take possession of the patent title.

We believe this is an egregious case of non-disclosure. The same three inventors are listed for each of the four patents. Collectively they were the principal investigators in NIH grants involving more than $66 million.

- According to the NIH RePORTER database, from 1988 to 2018, William Klunk was the principal investigator for grants obtained from the NIH consisting of 52 projects, 35 sub-projects and a total funding amount of $47,209,483.

---

[1] Bayh-Dole Obligations to Disclose Federal Funding in Patented Inventions. KEI Briefing Note: 2018:1. Andrew Goldman. Revised March 16, 2018.

- From 1986 to 2018, Chester A. Mathis, Jr. received NIH grants consisting of 31 projects and 12 subprojects with a total funding amount of $14,936,292.
- From 2003 to 2013, Yanming Wang was listed as the principal investigator for 19 NIH projects involving $4,116,038 of funding.

This actually understates the amount of federal funding involved, since the inventors have also received NIH research contracts and funding from the Department of Energy for this research.

The inventors have made references to NIH and DOE funding of their work in papers describing the inventions, but did not report the grants on the patents, and the patents do not appear in the NIH RePORTER database.

The patents were subsequently licensed to GE Healthcare. We believe the public interest would be served if the patents were licensed on a non-exclusive basis, permitting more competition in the use of the inventions, resulting in greater innovation and lower prices. Lower prices for flutemetamol F 18 may expand access to the test, which, as Medicare describes, “may be clinically useful in the work up and management of patients with cognitive impairment who are being evaluated for possible Alzheimer's disease or other causes of cognitive decline.”[2]

Finally, we note that this one of several letters we have sent to the HHS and/or the NIH, regarding failure of NIH grant recipients to disclose federal funding. We are still waiting to hear the conclusions of investigations regarding Cold Spring Harbor patents on nusinersen (trade name Spinraza), the Pharmasset/Gilead patent on sofosbuvir, the Dana Farber Cancer Institute patents on midostaurin (Trade name Rydapt), multiple institutions’ (including an NIH-funded project at a foreign university) patents on Exondys 51, and the University of Pennsylvania patents on Lomitapide (trade name Juxtapid). We are making these inquiries as a public service, to ensure the public has the opportunity to benefit from the safeguards and public interest provisions in the Bayh-Dole Act, including the obligation by patent holders to make the inventions available to the public on reasonable terms, the ability of the NIH to ensure broad use of inventions for research purposes, and the requirements in the Bayh-Dole Act for domestic manufacturing of products, among other requirements.

Sincerely,

James Love

James Love, Director, KEI
james.love@keionline.org
+1.202.332.2670

---

[2] https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Amyloid-PET.html

Attachments

1. Vizamyl (INN flutemetamol F 18): Failures to disclose NIH funding for four patents in the FDA Orange Book invented by William Klunk, Chester Mathis, Jr., and Yanming Wang, and assigned to the University of Pittsburgh. Knowledge Ecology International, May 18, 2018.
2. KEI-Briefing-Note-2018-1

Cc:

Dr. Francis Collins, Director, the National Institutes of Health: Francis.Collins@nih.hhs.gov

The Honorable Daniel R. Levinson, Inspector General, Office of Inspector General (OIG), HHS, Dan.Levinson@oig.hhs.gov

Ann M. Hammersla, J.D., Director, Division of Extramural Inventions and Technology Resources Office of Policy for Extramural Research Administration, hammerslaa@od.nih.gov

Rep. Tom Cole, Oklahoma, Chairman, Labor, Health and Human Services, Education, and Related Agencies, Committee on Appropriations, House of Representatives.

Rep. Rosa DeLauro, Connecticut, Ranking Member, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, Committee on Appropriations, House of Representatives.

Roy Blunt, Chair, Labor, Health and Human Services, Education and Related Agencies, Committee on Appropriations, U.S. Senate

Patty Murray, Ranking Member, Labor, Health and Human Services, Education and Related Agencies, Committee on Appropriations, U.S. Senate

Vizamyl (INN Flutemetamol F 18)

Failures to disclose NIH funding for four patents in the FDA Orange Book invented by William Klunk, Chester Mathis, Jr., and Yanming Wang, and assigned to the University of Pittsburgh

Knowledge Ecology International
May 18, 2018

Table of Contents

Introduction **2**

What Does Vizamyl Do? **3**

The Orange Book Patents for Vizamyl **4**
- Table 1: The Orange Book Patents for Vizamyl 4

The Klunk, Mathis, and Wang Patents that Failed to Disclose Federal Funding **4**
- Table 2: The Four Amyloid Klunk, Mathis and Wang Patents 4
- Table 3: NIH-Funded Projects to the University of Pittsburgh from Fiscal Years 1988 to 1999 Listing William Klunk as PI 6
- Table 4: NIH-Funded Projects to the University of Pittsburgh from Fiscal Years 2001 to 2002 Listing William Klunk as PI 7
- Table 5: The Eight R01 AG018402 Projects Listing Chester Mathis as the PI and the University of Pittsburgh as the Institution 10
- Table 6: The Ten P50 AG005133 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution 11
- Table 7: The Five K02 AG001039 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution 12
- Table 8: The Five R01 AG020226 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution 12
- Table 9: The Eleven R37 AG025516 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution 13
- Table 10: The Nineteen P01 AG025204 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution 14

Additional Notes on Research Grants from the National Institutes of Health **16**
- NIH Grants to William Klunk Cited in a 2003 Paper 16

NIH Grants to Chester Mathis Cited in a 2004 Paper **16**

NIH Grants to Yanming Wang **17**

Table 11: Five NIH Grants to Yanming Wang from 2003-2007 Mentioning Amyloid-based Screening for Alzheimer's and Dementia 19
Why the Wang Grants are Related to the Inventions 19

The Vizamyl Prices 20

Requested Remedies for Non-disclosure 20

ANNEX 1: Select News Reports and Other Background on Vizamyl 21

ANNEX 2: NIH Grants to the University of Pittsburgh with William E. Klunk Listed as Principal Investigator, with Search Term "Amyloid" 21

ANNEX 3: Eighteen Patents Assigned to the University of Pittsburgh that List William E. Klunk as the Inventor 24

ANNEX 4: NIH Grants to the University of Pittsburgh with Chester A. Mathis Listed as Principal Investigator, with Search Term "Amyloid" 25

Introduction

Knowledge Ecology International (KEI) asks the National Institutes of Health (NIH) to investigate whether there has been a failure to disclose NIH research funding on four patents granted that list William E. Klunk, Chester A. Mathis, Jr., and Yanming Wang as inventors. All four patents are assigned to the University of Pittsburgh.

The patents are listed as the first four patents (out of five patents) in the FDA Orange Book for the drug Vizamyl (INN flutemetamol, marketed by GE Healthcare), a nuclear imaging agent for the visualization of β-amyloid neuritic plaque density in patients being evaluated for cognitive disorders such as Alzheimer's disease.

Each of the three inventors received numerous research grants and contracts from the NIH and other federal agencies.

According to the NIH RePORTER database, from 1988 to 2018, William Klunk was the principal investigator for grants obtained from the National Institute of Health, consisting of 52 projects, 35 sub-projects and a total funding amount of $47,209,483.

From 1986 to 2018, Chester A. Mathis, Jr. received NIH grants consisting of 31 projects and 12 subprojects with a total funding amount of $14,936,292.

From 2003 to 2013, Yanming Wang was listed as the principal investigator for 19 NIH projects involving $4,116,038 of funding.

Many of the NIH grants are directly related to the four patented inventions. In addition to the grants disclosed in the NIH RePORTER database, the inventors have disclosed additional research contracts or grants related to the invention from the NIH and the U.S. Department of Energy, in various academic papers describing the inventions.

The inventions are important. William Klunk and Chester Mathis received a $100,000 Potamkin Prize award in 2008 for their research on Alzheimer's disease. Specifically, the prize was awarded for the invention and development of Pittsburgh Compound B (PiB), a radioactive amyloid plaque imaging compound that enables visualization of the β-amyloid plaque deposits (which disrupt the function of brain cells) and distinguishes between the diagnosis of Alzheimer's disease and other types of dementia.[1]

Vizamyl is available in 10 or 30 mL multi-dose glass vials at a strength of 150 MBq/mL (4.05 mCi/mL), the price of 1 vial (5 mCi) is approximately $28,000. Medicare restricts reimbursements for the tests.[2]

KEI is asking the NIH to take title to the patents, which is an available remedy under the Bayh-Dole Act for non-disclosure of federal funding of patented inventions. At a minimum, the Department of Health and Human Services should require the University of Pittsburgh to correct the failure to disclose the NIH grants.

What Does Vizamyl Do?

GE Healthcare[3] provides the following information on Vizamyl:

> Vizamyl is an imaging drug (also called a tracer) that is injected into a person's bloodstream before a positron-emission tomography (PET) scan is performed. Currently, Vizamyl is the first-and-only imaging drug approved to provide color PET images that help your doctor estimate the amount of a protein called beta amyloid in the brain.
>
> Although most people will develop some beta amyloid in the brain during aging, those with Alzheimer's disease tend to develop more than those who do not have the disease.
>
> ...A short time after Vizamyl is injected into the bloodstream, it will attach to beta amyloid in the brain. An imaging device called a PET scanner will then take color images of the brain. A radiologist can use these images to estimate how much beta amyloid there is.

---

[1] Klunk and Mathis Win Prestigious Potamkin Prize For Alzheimer's Research. 2008

[2] Final Decision Memorandum for: CAG-00431N Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease, September 27, 2013. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=265

[3] About Vizamyl. 2017

In 2010, the Centers for Disease Control reported an estimate of 5.4 million Americans affected by Alzheimer's, ranking the illness the "sixth leading cause of death among all adults and the fifth leading cause of death for those aged 65 or older".[4]

The Orange Book Patents for Vizamyl

The May 10, 2018 version of the FDA Orange Book lists five patents for Vizamyl. Four patents were assigned to the University of Pittsburgh and one was assigned to GE Healthcare Limited, in Buckinghamshire, Great Britain.

Table 1: The Orange Book Patents for Vizamyl

Patent Number	Grant	Expiration	Inventors	Assignee
7270800	9/18/2007	09/03/2025	Klunk; William E. (Pittsburgh, PA), Mathis, Jr.; Chester A. (Pittsburgh, PA), Wang; Yanming (Imperial, PA)	University of Pittsburgh
7351401	4/1/2008	01/24/2023	Klunk; William E. (Pittsburgh, PA), Mathis, Jr.; Chester A. (Pittsburgh, PA), Wang; Yanming (Imperial, PA)	University of Pittsburgh
8236282	8/8/2012	05/21/2024	Klunk; William E. (Pittsburgh, PA), Mathis, Jr.; Chester A. (Pittsburgh, PA), Wang; Yanming (Imperial, PA)	University of Pittsburgh
8691185	4/8/2014	01/24/2023	Klunk; William E. (Pittsburgh, PA), Mathis, Jr.; Chester A. (Pittsburgh, PA), Wang; Yanming (Imperial, PA)	University of Pittsburgh
8916131	12/23/2014	09/16/2028	Roed; Line (Oslo, NO), Peterson; Sarah Elizabeth (Amersham, GB)	GE Healthcare Limited (Buckinghamshire, GB)

The Klunk, Mathis, and Wang Patents that Failed to Disclose Federal Funding

The four University of Pittsburgh patents failed to disclose federal funding in the invention. The priority, file and grant dates, title, and abstract for the patents are listed in Table 2.

Table 2: The Four Amyloid Klunk, Mathis and Wang Patents

Patent Number	**Priority Date**	**File Date**	**Grant Date**	**Title**	**Abstract**
7270800	8/24/2000	3/14/2003	9/18/2007	Thioflavin derivatives for use in antemortem diagnosis of	This invention relates to novel thioflavin derivatives, methods of using the derivatives in, for example, in vivo imaging of patients having neuritic plaques, pharmaceutical compositions comprising the thioflavin

---

[4] Promoting Health and Independence for an Aging Population At A Glance 2017. September 12, 2017

				Alzheimer's disease and in vivo imaging and prevention of amyloid deposition	derivatives and method of synthesizing the compounds. The compounds find particular use in the diagnosis and treatment of patients having diseases where accumulation of neuritic plaques are prevalent. The disease states or maladies include but are not limited to Alzheimer's disease, familial Alzheimer's disease, Down's Syndrome and homozygotes for the apolipoprotein E4 allele.
7351401	8/24/2000	6/3/2004	4/01/2008	Thioflavin derivatives for use in the antemortem diagnosis of Alzheimers disease and in vivo imaging and prevention of amyloid deposition	This invention relates to novel thioflavin derivatives, methods of using the derivatives in, for example, in vivo imaging of patients having neuritic plaques, pharmaceutical compositions comprising the thioflavin derivatives and method of synthesizing the compounds. The compounds find particular use in the diagnosis and treatment of patients having diseases where accumulation of neuritic plaques are prevalent. The disease states or maladies include but are not limited to Alzheimer's Disease, familial Alzheimer's Disease, Down's Syndrome and homozygotes for the apolipoprotein E4 allele.
8236282	8/22/2003	9/30/2009	8/7/2012	Benzothiazole derivative compounds, compositions and uses	This invention provides benzothiazole derivative compounds, compositions comprising such compounds, methods of preparing such compounds, and methods of using such compounds for detecting amyloid deposit(s) and for diagnosing a disease, disorder or condition characterized by amyloid deposit(s).
8691185	08/22/2003	7/12/2012	4/8/2014	Benzothiazole derivative compounds, compositions and uses	This invention provides benzothiazole derivative compounds, compositions comprising such compounds, methods of preparing such compounds, and methods of using such compounds for detecting amyloid deposit(s) and for diagnosing a disease, disorder or condition characterized by amyloid deposit(s).

Note that all four patents have the same three inventors (Klunk, Mathis and Wang). The first two patents have the same title, abstract and priority date. The last two patents have the same title, abstract and priority date.

The 7,270,800 and 7,351,401 patents

The 7,270,800 and 7,351,401 patents have the same three inventors (Klunk, Mathis and Wang), title and abstract, with somewhat different claims. The inventions involve novel thioflavin derivatives, and their use in in vivo imaging, for diagnosis and treatment of patients having diseases where accumulation of neuritic plaques are prevalent, including but not limited to Alzheimer's disease. The priority date for both patents is August 24, 2000, and the filing dates were May 14, 2003 and June 3, 2004.

Table 3 lists eight NIH-funded projects by the University of Pittsburgh from 1988 to 1999 that list William Klunk as the Principal Investigator. This is the time leading up to the priority date for patents 7,270,800 and 7,351,401.

Table 3: NIH-Funded Projects to the University of Pittsburgh from Fiscal Years 1988 to 1999 Listing William Klunk as PI

Project Number	Title	FY	Agency	Amount
1 F32 AG005443 01	MOLECULAR PROBES FOR ALZHEIMER BETA-AMYLOID PROTEIN	1988	NIA	$27,000
5 F32 AG005443 02	MOLECULAR PROBES FOR ALZHEIMER BETA-AMYLOID PROTEIN	1989	NIA	$31,750
5 R01 AG005657 06	NMR STUDIES OF BRAIN AGING IN ALZHEIMER'S DISEASE	1990	NIA	$139,105
1 R29 MH053310 01A1	CLINICAL METABOLIC CORRELATION IN DEMENTIA BY PROTON NMR	1995	NIMH	$98,405
5 R29 MH053310 02	CLINICAL METABOLIC CORRELATION IN DEMENTIA BY PROTON NMR	1996	NIMH	$101,910
5 R29 MH053310 03	CLINICAL METABOLIC CORRELATION IN DEMENTIA BY PROTON NMR	1997	NIMH	$105,204
5 R29 MH053310 04	CLINICAL METABOLIC CORRELATION IN DEMENTIA BY PROTON NMR	1998	NIMH	$108,621
5 R29 MH053310 05	CLINICAL METABOLIC CORRELATION IN DEMENTIA BY PROTON NMR	1999	NIMH	$112,536

The budget end date for project 5R29MH053310-05 was June 30, 2000, less than two months before the priority date of the two patents. The abstract for that grant reads as follows:

Project Number: 5R29MH053310-05
Contact PI / Project Leader: Klunk, William E
Title: Clinical Metabolic Correlation In Dementia By Proton NMR
Awardee Organization: University Of Pittsburgh At Pittsburgh

Abstract Text:
This study proposes to perform a clinical-metabolic-neuropathological correlation in **dementia**, in particular, primary degenerative **dementia** of the **Alzheimer** type (AD). We will use clinical data on behavior, mood, function, and cognition obtained in the year preceding death as markers of severity. Proton nuclear **magnetic resonance spectroscopy** (1/H **MRS**) will be used to analyze 6 brain areas obtained at autopsy from 75 **Alzheimer's disease** (AD), 25 controls, and 15 non-AD demented controls over 5 years. The first goal is to broaden the metabolic understanding of AD and to delineate clinical-metabolic-neuropathological correlations in a way that may provide insights into the timing of pathogenetic events over the course of this dementing illness. The second goal is to provide a detailed in vitro database for future extensions of this study into 1/H **MRS** studies of living patients with AD. No such detailed database currently exists. The metabolites measurable by 1/H MRS include N-acetyl-L-aspartate (NAA), L-glutamate, GABA, glutamine, myo-inositol, choline- containing compounds, creative and others. NAA is important because it is a putative neuronal marker easily detected by **in vitro** and **in vivo** 1/H **MRS** and can give an estimate of neuronal survival. Much like senile plaques and **neurofibrillary tangles**, NAA can be considered a new candidate marker of the neuropathological severity of **dementia**. The excitatory and inhibitory

amino acids also play key roles in excitotoxic theories of several **dementias**. The choline-containing compounds include a phosphodiester which is a product of membrane degradation. In addition to determining differences between AD and control, demented non-AD brains will be examined to determine the **specificity** of the changes for AD. Clinical-metabolic and metabolic-neuropathologic correlations to NAA, **senile plaques**, and **neurofibrillary tangles** will be done in an attempt to determine which changes represent early, potentially causative, events and which changes are more likely secondary effects of neurodegeneration. In addition, a separately funded study will be analyzing the tissue by 31/P **MRS** and the levels of the membrane metabolites, phosphomonoesters and phosphodiesters, will be available for correlative studies as well. We hypothesize that markers of membrane proliferation and neuronal inhibition will be elevated early in the disease and decreased at later stages. In contrast, markers of membrane degeneration and excitotoxicity will be elevated at later stages. Preliminary results suggest that the i**n vitro** 1/H **MRS** studies proposed in this application could provide information that is valuable in both a diagnostic and pathophysiologic sense and be readily extended to non-invasive, longitudinal studies of living patients which could aid in monitoring the course of the illness and tracking efficacy of experimental therapies.

The 8,236,282 and 8,691,185 patents

The 8,236,282 and 8,691,185 patents have the same three inventors (Klunk, Mathis and Wang), title and abstract, with somewhat different claims. The inventions involve compositions and methods of preparing benzothiazole derivatives, for the detection and diagnosis of diseases characterized by amyloid deposits. The priority date for both patents is August 22, 2003. The filing dates were September 30, 2009 and July 12, 2012.

Table 4 lists four NIH-funded projects by the University of Pittsburgh from 2001 to 2002 that list William Klunk as the Principal Investigator.

Table 4: NIH-Funded Projects to the University of Pittsburgh from Fiscal Years 2001 to 2002 Listing William Klunk as PI

Project Number	Title	FY	Agency	Amount
1K02AG001039 01A1	PET IMAGING PROBES FOR AMYLOID IN ALZHEIMERS AND AGING	2001	NIA	$97,686
1R01AG020226 01	PET TRACERS TO MONITOR VACCINE AND IMMUNE THERAPY FOR AD	2001	NIA	$366,936
5K02AG001039 02	PET IMAGING PROBES FOR AMYLOID IN ALZHEIMERS AND AGING	2002	NIA	$97,686
5R01AG020226 02	PET TRACERS TO MONITOR VACCINE AND IMMUNE THERAPY FOR AD	2002	NIA	$353,050

The budget end date for project 5R01AG020226-02 was July 31, 2003, less than two months before the priority date for the 8,236,282 and 8,691,185 patents, and right before the filing of the 7,270,800 and 7,351,401 patents.

The abstract for that grant reads as follows:

Project Number: 5R01AG020226-02
Contact PI / Project Leader: Klunk, William E
Title: PET Tracers To Monitor Vaccine And Immune Therapy For AD
Awardee Organization: University Of Pittsburgh At Pittsburgh

Abstract Text:
DESCRIPTION (provided by the applicant): The deposition of beta-sheet fibrils in **Alzheimer's disease (AD)** brain has been hypothesized to be the primary cause of this devastating neurodegenerative disease. These deposits include the **amyloid-beta** (Abeta) protein in **plaques** and vascular amyloid and hyper-phosphorylated tau protein in neurofibrillary tangles, dystrophic neurites and neuropil threads. Despite the presence of this characteristic neuropathology and its critical importance in the pathophysiology of the disease, no non-invasive technique has been validated to assess the presence of these deposits in living patients. The absence of such a technique hinders early and presymptomatic diagnosis and will severely hinder the development of immune therapies aimed at prevention or reversal of beta-sheet fibril deposition. Over the past decade, our laboratory has worked to develop an in vivo **beta-sheet amyloid** fibril imaging agent. This work has resulted in a promising lead agent, [N-methyl-11C]2(-4'-methylaminophenyl-**benzothiazol**e (or [11C]BTA-1) which: 1) readily enters and clears from normal rodent and baboon brain; 2) binds to synthetic Abeta with nanomolar affinity; 3) specifically stains **plaques** and **tangles** in post-mortem AD brain; 4) binds to homogenates of post-mortem AD brain frontal cortex at >10-fold higher levels than aged control brain and non-AD demented brain samples, but shows no increased **binding** in AD **cerebellum**; and 5) shows no evidence of acute toxicity in preliminary studies. Furthermore, preliminary in vivo studies using APP transgenic mice and low resolution **PET scanning** show increased accumulation in the transgenic mice. In this study, we propose to validate the use of [11C]BTA-1 for in vivo **amyloid imaging** in PS/APP transgenic mice using a small animal microPET scanner. We will correlate in vivo results with: 1) quantitative immunohistochemical and histochemical measures of amyloid deposition; 2) Abeta ELISA; and 3) ex-vivo [11C]**BTA-1** levels and post-mortem [3H]**BTA-1** binding. We will show feasibility of longitudinal studies of the [11C]BTA-1/microPET technique in PS/APP mice and apply the technique to study an immune therapy protocol in these mice. Our goal is to provide a tool for use by investigators developing improved immune therapy protocols in transgenic mice, thus speeding progress in this area. However, because all of the techniques developed in this proposal apply directly to human studies, completion of this study will greatly speed the development of this technology for use in human studies of anti-amyloid therapies (immune therapy and secretase inhibitor therapies).

Description of the 7,270,800; 7,351,401; 8,236,282 and 8,691,185 patents

Thioflavin T is a benzothiazole compound, a fluorescent marker or a dye, that is used for the visualization and quantification of amyloid (misfolded protein aggregates found in the brains of patients diagnosed with Alzheimer's disease). Amyloids are made up of beta sheet fibrils or structures. The binding of Thioflavin T compounds to the amyloids' beta sheets displays a major increase in fluorescence intensity, allowing quantification of amyloids and diagnosis.[5]

In 2008, two of the patents' inventors, Klunk and Mathis, published a paper in the *Journal of Alzheimer Disease and Associated Disorders*, titled "Whatever happened to Pittsburgh Compound-A?"[6] The paper provides an overview of research undertaken in order to obtain the desired and most effective thioflavin derivative for the diagnosis of Alzheimer's disease. The following statements were provided:

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[5] (2010). Biancalana M; Koide S. "Molecular mechanism of Thioflavin-T binding to amyloid fibrils" *Biochim Biophys Acta.* 1804(7):1405-12.

[6] (2008). Klunk WE; Mathis CA. "Whatever happened to Pittsburgh Compound-A?" *Alzheimer Dis Assoc Disord.* 22(3):198-203.

> ". . . Pittsburgh Compound-A (PiA) represents one of the early thioflavin-T derivatives made in our amyloid-imaging tracer development program at the University of Pittsburgh.
>
> . . . For more than a decade, we struggled with manipulating the Congo red pharmacophore into a suitable positron emission tomography (PET) amyloid tracer with only limited success. This was primarily a result of the poor brain entry of this class of compounds.
>
> . . . The transition away from the Congo red derivatives such as the X-series began in November 1999. From that time through our present work with fluorine-18–labeled PiB derivatives, we have synthesized and tested over 350 thioflavin-T derivatives.
>
> . . . BTA-1 (PiA) was the seventh of the thioflavin-T derivatives and was first tested with in vitro binding studies and ex vivo mouse brain entry studies in April 2000, just 5 months into our thioflavin-T exploration program.
>
> . . . It is worth noting that we began the approval process for human studies simultaneously in Sweden and in the United States in 2001, understanding that it would take longer to begin our studies in Pittsburgh than it would to begin the Uppsala arm of this study. That process included toxicologic evaluation of the lead compound funded by a special National Institute on Aging (NIA) mechanism (NIA contract, N01- AG-9-2117).
>
> . . . NIA had already approved funding for toxicologic evaluation of Pittsburgh Compound-A, when the suggestion came up at our weekly chemistry meeting something to the effect of, "I've been looking at the data and thinking, and I don't think BTA-1 is the best compound. I think we should go with 6-OH-BTA-1 [the original name for PiB], because it is cleared from normal brain much better." It should not be surprising that this suggestion was initially met with a degree of inertia on both sides of the Atlantic.
>
> . . . PiB was the 23rd compound synthesized and tested in our thioflavin-T program in July 2000, so it had been on the (lab)books for more than a year before the first human study. The affinities of Pittsburgh Compound-A and PiB were never convincingly different in binding studies using Aβ fibrils or AD brain homogenates, but the more rapid clearance of PiB from normal animal brain was evident very early on.
>
> . . . The case was made as follows: when compared with several other proven dopamine and serotonin neuroreceptor radiotracers on "level ground," PiB fit the profile of a good tracer and Pittsburgh Compound-A did not."

The research paper further discloses how the correct thioflavin derivatives (PiA and PiB) were derived for the diagnosis of Alzheimer's disease, and notes some of the relevant time periods.

The following statements were made regarding funding:

> "Funding support for portions of the development program was provided by grants from The National Institutes of Health (R01 AG018402, P50 AG005133, K02 AG001039, R01 AG020226, R01 MH070729, K01 MH001976, R37 AG025516, P01 AG025204), the Alzheimer's Association (TLL-01-3381), GE Healthcare and the US Department of Energy (DE-FD02-03 ER63590)."

With the exception of grants R01 MH070729 and K01 MH001976 (PI Julie Price), all the other grants listed identified either William Klunk or Chester Mathis as the Principal Investigators.

Grant R01 AG018402

Using the NIH RePORTER database, we searched for the grant R01 AG018402. There were eight projects funded under grant R01 AG018402, where Chester Mathis was the Principal Investigator, from 2001 to 2010. The organization receiving the funding was the University of Pittsburgh.

Table 5: The Eight R01 AG018402 Projects Listing Chester Mathis as the PI and the University of Pittsburgh as the Institution

Project	Project Title	FY	Total Cost
1R01AG018402-01A1	AMYLOID IMAGING AGENTS FOR POSITRON EMISSION TOMOGRAPHY	2001	*$350,525*
5R01AG018402-02	AMYLOID IMAGING AGENTS FOR POSITRON EMISSION TOMOGRAPHY	2002	*$349,224*
5R01AG018402-03	AMYLOID IMAGING AGENTS FOR POSITRON EMISSION TOMOGRAPHY	2003	*$347,922*
5R01AG018402-04	AMYLOID IMAGING AGENTS FOR POSITRON EMISSION TOMOGRAPHY	2004	*$346,619*
2R01AG018402-05	AMYLOID IMAGING AGENTS FOR POSITION EMISSION TOMOGRAPHY	2007	*$339,851*
5R01AG018402-06	AMYLOID IMAGING AGENTS FOR POSITION EMISSION TOMOGRAPHY	2008	*$376,408*
5R01AG018402-07	AMYLOID IMAGING AGENTS FOR POSITION EMISSION TOMOGRAPHY	2009	*$394,437*

5R01AG018402-08	AMYLOID IMAGING AGENTS FOR POSITION EMISSION TOMOGRAPHY	2010	*$357,159*

Grant P50 AG005133

Using the NIH RePORTER database, we searched for the grant P50 AG005133. There were ten sub-projects funded under grant P50 AG005133, where William Klunk was the Principal Investigator, from 2005 to 2014.The organization receiving the funding was the University of Pittsburgh.

Table 6: The Ten P50 AG005133 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution

Project	Project Title	FY	Total Cost
2P50AG005133-22	NATURAL HISTORY OF AMYLOID DEPOSITION IN FAMILIAL AD	2005	*$185,625*
5P50AG005133-23	NATURAL HISTORY OF AMYLOID DEPOSITION IN FAMILIAL AD	2006	*$128,746*
5P50AG005133-24	NATURAL HISTORY OF AMYLOID DEPOSITION IN FAMILIAL ALZHEIMERS DISEASE	2007	*$214,077*
5P50AG005133-25	NATURAL HISTORY OF AMYLOID DEPOSITION IN FAMILIAL ALZHEIMERS DISEASE	2008	*$215,088*
5P50AG005133-26	NATURAL HISTORY OF AMYLOID DEPOSITION IN FAMILIAL ALZHEIMERS DISEASE	2009	*$221,371*
2P50AG005133-27	NATURAL HISTORY OF AMYLOID DEPOSITION FAMILIAL AD	2010	*$171,025*
5P50AG005133-28	NATURAL HISTORY OF AMYLOID DEPOSITION FAMILIAL AD	2011	*$199,286*
5P50AG005133-29	NATURAL HISTORY OF AMYLOID DEPOSITION FAMILIAL AD	2012	*$182,113*
5P50AG005133-30	NATURAL HISTORY OF AMYLOID DEPOSITION FAMILIAL AD	2013	*$170,365*
5P50AG005133-31	NATURAL HISTORY OF AMYLOID DEPOSITION FAMILIAL AD	2014	*$182,280*

Grant K02 AG001039

Using the NIH RePORTER database, we searched for the grant K02 AG001039. There were five projects funded under grant K02 AG001039, where William Klunk was the Principal Investigator, from 2001 to 2005. The organization receiving the funding was the University of Pittsburgh.

Table 7: The Five K02 AG001039 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution

Project	Project Title	FY	Total Cost
1K02AG001039-01A1	PET IMAGING PROBES FOR AMYLOID IN ALZHEIMERS AND AGING	2001	*$97,686*
5K02AG001039-02	PET IMAGING PROBES FOR AMYLOID IN ALZHEIMERS AND AGING	2002	*$97,686*
5K02AG001039-03	PET IMAGING PROBES FOR AMYLOID IN ALZHEIMERS AND AGING	2003	*$97,686*
5K02AG001039-04	PET IMAGING PROBES FOR AMYLOID IN ALZHEIMERS AND AGING	2004	*$97,686*
5K02AG001039-05	PET IMAGING PROBES FOR AMYLOID IN ALZHEIMERS AND AGING	2005	*$97,686*

Grant R01 AG020226

Using the NIH RePORTER database, we searched for the grant R01 AG020226. There were five projects funded under grant R01 AG020226, where William Klunk was the Principal Investigator, from 2001 to 2005. The organization receiving the funding was the University of Pittsburgh.

Table 8: The Five R01 AG020226 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution

Project	Project Title	FY	Total Cost
1R01AG020226-01	PET TRACERS TO MONITOR VACCINE AND IMMUNE THERAPY FOR AD	2001	*$366,936*

5R01AG020226-02	PET TRACERS TO MONITOR VACCINE AND IMMUNE THERAPY FOR AD	2002	*$353,050*
5R01AG020226-03	PET TRACERS TO MONITOR VACCINE AND IMMUNE THERAPY FOR AD	2003	*$353,050*
5R01AG020226-04	PET TRACERS TO MONITOR VACCINE AND IMMUNE THERAPY FOR AD	2004	*$353,050*
5R01AG020226-05	PET TRACERS TO MONITOR VACCINE AND IMMUNE THERAPY FOR AD	2005	*$353,050*

Grant R37 AG025516

Using the NIH RePORTER database, we searched for the grant R37 AG025516. There were eleven projects funded under grant R37 AG025516, where William Klunk was the Principal Investigator, from 2005 to 2014. The organization receiving the funding was the University of Pittsburgh.

Table 9: The Eleven R37 AG025516 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution

Project	Project Title	FY	Total Cost
1R37AG025516-01	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2005	*$430,155*
5R37AG025516-02	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2006	*$459,594*
5R37AG025516-03	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2007	*$459,409*
5R37AG025516-04	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2008	*$449,361*
3R37AG025516-05S1	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2009	*$5,000*

5R37AG025516-05	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2009	*$362,933*
4R37AG025516-06	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2010	*$473,345*
5R37AG025516-07	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2011	*$481,954*
5R37AG025516-08	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2012	*$480,423*
5R37AG025516-09	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2013	*$441,934*
5R37AG025516-10	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2014	*$227,443*

Grant P01 AG025204

Using the NIH RePORTER database, we searched for the grant P01 AG025204. There were 36 projects funded under grant P01 AG025204, where William Klunk was the Principal Investigator, from 2005 to 2018. The organization receiving the funding was the University of Pittsburgh.

Of interest are the nineteen grants listed from years 2005-2012, prior to the filing dates for two of the patents.

Table 10: The Nineteen P01 AG025204 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution

Project	Project Title	FY	Total Cost
1P01AG025204-01	CROSS-SECTIONAL ASSESSMENT OF IN VIVO AMYLOID IN MCI AND AD	2005	*$157,425*
5P01AG025204-02	CROSS-SECTIONAL ASSESSMENT OF IN VIVO AMYLOID IN MCI AND AD	2006	*$172,602*
5P01AG025204-03	CROSS-SECTIONAL ASSESSMENT OF IN VIVO AMYLOID IN MCI AND AD	2007	*$298,271*
3P01AG025204-04S1	IN VIVOPIB PET AMYLOID IMAGING: NORMALS, MCI & DEMENTIA	2008	*$142,645*

5P01AG025204-04	CROSS-SECTIONAL ASSESSMENT OF IN VIVO AMYLOID IN MCI AND AD	2008	*$259,127*
5P01AG025204-04	IN VIVOPIB PET AMYLOID IMAGING: NORMALS, MCI & DEMENTIA	2008	*$1,031,916*
5P01AG025204-05	CROSS-SECTIONAL ASSESSMENT OF IN VIVO AMYLOID IN MCI AND AD	2009	*$360,047*
5P01AG025204-05	IN VIVOPIB PET AMYLOID IMAGING: NORMALS, MCI & DEMENTIA	2009	*$1,151,713*
2P01AG025204-06	ADMINISTRATIVE CORE	2010	*$129,363*
2P01AG0252040-06	MODULATORS OF COGNITIVE TRANSIFION FROM MCI TO AD	2010	*$301,836*
2P01AG025204-06	IN VIVO PIB PET AMYLOID IMAGING: NORMALS, MCI & DEMENTIA	2010	*$1,538,583*
5P01AG025204-07	ADMINISTRATIVE CORE	2011	*$126,512*
5P01AG025204-07	MODULATORS OF COGNITIVE TRANSIFION FROM MCI TO AD	2011	*$346,486*
5P01AG025204-07	QUANTITATIVE NEUROPATHOLOGICAL CORRELATES OF IN VIVO PIB RETENTION	2011	*$292,634*
5P01AG025204-07	IN VIVO PIB PET AMYLOID IMAGING: NORMALS, MCI & DEMENTIA	2011	*$1,482,584*
5P01AG025204-08	ADMINISTRATIVE CORE	2012	*$126,424*
5P01AG025204-08	MODULATORS OF COGNITIVE TRANSIFION FROM MCI TO AD	2012	*$337,923*
5P01AG025204-08	QUANTITATIVE NEUROPATHOLOGICAL CORRELATES OF IN VIVO PIB RETENTION	2012	*$287,620*
5P01AG025204-08	IN VIVO PIB PET AMYLOID IMAGING: NORMALS, MCI & DEMENTIA	2012	*$1,420,069*

Additional Notes on Research Grants from the National Institutes of Health

NIH Grants to William Klunk Cited in a 2003 Paper

In 2003, the patents' inventors, Klunk, Mathis and Wang, published a paper in the journal *Proceedings of the National Academy of Sciences of the United States of America* along with seven co-authors, titled "Four-dimensional multiphoton imaging of brain entry, amyloid binding, and clearance of an amyloid-beta ligand in transgenic mice."[7] The paper made disclosures regarding funding, including NIH grants to Mathis and Klunk:

> "...This work supported by National Institutes of Health Grants AG08487 (to B.T.H.), AG18402 (**to C.A.M.**), AG01039 (**to W.E.K.**), AG20226 (**to W.E.K.**), AG15453 (to B.T.H.), EB00768 (to B.J.B.), and AG020570 (to B.J.B.), an Alzheimer Association Pioneer Award (to B.T.H.), Alzheimer Association Grants IIRG-95-076 (to W.E.K.), TLL-01-3381 (to W.E.K.), and NIRG-00-2355 (to Y.W.), and Institute for the Study of Aging/American Federation for Aging Research Grant 210304 (to Y.W.)."

The abstract for Bacskai *et al.* 2003 reads as follows:

> "The lack of a specific biomarker makes preclinical diagnosis of **Alzheimer's disease** (AD) impossible, and it precludes assessment of therapies aimed at preventing or reversing the course of the disease. The development of a tool that enables direct, quantitative detection of the **amyloid-beta deposits** found in the disease would provide an excellent biomarker. This article demonstrates the real-time biodistribution kinetics of an imaging agent in transgenic mouse models of **AD**. Using multiphoton microscopy, **Pittsburgh compound B (PIB)** was imaged with sub-μm resolution in the brains of living transgenic mice during peripheral administration. **PIB** entered the brain quickly and labeled **amyloid deposits** within minutes. The nonspecific **binding** was cleared rapidly, whereas specific labeling was prolonged. WT mice showed rapid brain entry and clearance of **PIB** without any binding. These results demonstrate that the compound **PIB** has the properties required for a good amyloid-imaging agent in humans with or at risk for **AD**."

NIH Grants to Chester Mathis Cited in a 2004 Paper

In 2004, the patents inventors, Klunk, Mathis and Wang, published a paper in the journal *Annals of Neurology* along with eighteen co-authors, titled "Imaging brain amyloid in Alzheimer's disease with Pittsburgh Compound-B."[8] PubMed provides the following information on the grant support:

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[7] (2003). Bacskai BJ; Hickey GA; Skoch J; Kajdasz ST; Wang Y; Huang GF; Mathis CA; Klunk WE; Hyman BT. "Four-dimensional multiphoton imaging of brain entry, amyloid binding, and clearance of an amyloid-beta ligand in transgenic mice." *Proc Natl Acad Sci U S A.* 100(21):12462-7.

> "Grant support
> AG 01039/AG/NIA NIH HHS/United States
> **AG 05133/AG/NIA NIH HHS/United States**
> **AG 18402/AG/NIA NIH HHS/United States**
> AG 20226/AG/NIA NIH HHS/United States"

The abstract for Klunk *et al.* 2004 reads as follows:

> "This report describes the first human study of a novel **amyloid-imaging positron emission tomography (PET)** tracer, termed **Pittsburgh Compound-B (PIB)**, in 16 patients with diagnosed mild **AD** and 9 controls. Compared with controls, **AD** patients typically showed marked retention of **PIB** in areas of association cortex known to contain large amounts of amyloid deposits in **AD**. In the **AD** patient group, **PIB** retention was increased most prominently in frontal cortex (1.94-fold, p = 0.0001). Large increases also were observed in parietal (1.71-fold, p = 0.0002), temporal (1.52-fold, p = 0.002), and occipital (1.54-fold, p = 0.002) cortex and the striatum (1.76-fold, p = 0.0001). **PIB** retention was equivalent in AD patients and controls in areas known to be relatively unaffected by **amyloid** deposition (such as subcortical white matter, pons, and cerebellum). Studies in three young (21 years) and six older healthy controls (69.5 ± 11 years) showed low PIB retention in cortical areas and no significant group differences between young and older controls. In cortical areas, PIB retention correlated inversely with cerebral glucose metabolism determined with 18F-fluorodeoxyglucose. This relationship was most robust in the parietal cortex (r = −0.72; p = 0.0001). The results suggest that **PET** imaging with the novel tracer, PIB, can provide quantitative information on **amyloid deposits** in living subjects.

NIH Grants to Yanming Wang

In 2004, the patents' inventors, Klunk, Mathis and Wang, published a paper in the *Journal of Molecular Neuroscience* along with four co-authors, titled "development of a PET/SPECT agent for amyloid imaging in Alzheimer's disease."[9] PubMed provides the following information on the grant support:

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[8] (2004). Klunk WE; Engler H; Nordberg A; Wang Y; Blomqvist G; Holt DP; Bergström M; Savitcheva I; Huang GF; Estrada S; Ausén B; Debnath ML; Barletta J; Price JC; Sandell J; Lopresti BJ; Wall A; Koivisto P; Antoni G; Mathis CA; Långström B. "Imaging brain amyloid in Alzheimer's disease with Pittsburgh Compound-B." *Ann Neurol.* 55(3):306-19.

[9] (2004). Wang Y; Klunk WE; Debnath ML; Huang GF; Holt DP; Shao L; Mathis CA. "Development of a PET/SPECT agent for amyloid imaging in Alzheimer's disease." *J Mol Neurosci.* 24(1):55-62.

> "Grant support
> AG01039/AG/NIA NIH HHS/United States
> AG05133/AG/NIA NIH HHS/United States
> AG18402/AG/NIA NIH HHS/United States
> AG20226/AG/NIA NIH HHS/United States
> **AG22048-01A1/AG/NIA NIH HHS/United States**"

The abstract for Wang *et al.* 2004 reads as follows:

> "In the search for a cure for **Alzheimer's disease (AD)**, efforts have been focused on preventing or reversing **amyloid deposition** in the **brain**. Efficacy evaluation of these antiamyloid therapies would greatly benefit from development of a tool for the **in vivo** detection and quantitation of **amyloid deposits** in the brain. Toward this goal, we have developed a series of **benzothiazole derivatives** as **amyloid-imaging agents** for **positron emission tomography (PET)**. To extend the potential of these **amyloid-imaging agents** for routine clinical studies, we also set out to develop iodinated **benzothiazole derivatives** that could be used as dual agents for either PET or the complementary s**ingle photon emission computed tomography (SPECT)**. Such dual agents would permit **PET** or **SPECT** studies using radiotracers with the same chemical identity but labeled with different radionuclides. This would facilitate the validation of clinical **SPECT** studies, based on quantitative **PET** studies. In this work we report the synthesis and biological evaluation of a potent, selective, and brain-permeable benzothiazole compound, 2-(3'-iodo-4'-methylaminophenyl)-6-hydroxy-benzothialzole, termed 6-OH-BTA-1-3'-I (4), which can be **radiolabeled** with either positron-emitting carbon-11 or single photon-emitting iodine-125/iodine-123. The synthesis and radiolabeling of [125I]4 or [11C]4 were achieved through direct iodination with sodium [125I]iodide in the presence of chloramine T or through radiomethylation with [11C]CH3I. **In vitro amyloid binding** assays indicated that [125I]4 bound to **amyloid deposits** in a saturable manner and exhibited affinities in the nanomolar concentration range. Binding studies of [125I]4 to postmortem human brain homogenates also showed preference of binding to frontal cortex in the **AD** homogenates relative to age-matched control **homogenates** or **cerebellum** from either **AD** or control. **In vivo** pharmacokinetic studies in normal mice following iv injection of [11C]4 indicated that the **radioligand** entered the **brain** readily at early time points and cleared from the **brain** rapidly at later time points with a 2- to 30-min ratio >3. These results suggest that the new radioiodinated **benzothiazole ligand** might be useful as a surrogate marker for the in vivo quantitation of **amyloid deposition** in human brain for use with either **PET** or **SPECT**."

According to the NIH RePORTER database, Yanming Wang received a total of $602,463 to support five projects that mention amyloid and involve diagnostics tests for dementia and/or Alzheimer's disease.

Table 11: Five NIH Grants to Yanming Wang from 2003-2007 Mentioning Amyloid-based Screening for Alzheimer's and Dementia

Grant Number	Title	Budget Start Date	Budget End Date	Agency
1K25AG022048-01A1	QUANTITATIVE IMAGING OF AMYLOID DEPOSITS IN AD AND AGING	9/30/2003	8/31/2004	NIA
7K25AG022048-02	QUANTITATIVE IMAGING OF AMYLOID DEPOSITS IN AD AND AGING	9/15/2004	8/31/2005	NIA
5K25AG022048-03	QUANTITATIVE IMAGING OF AMYLOID DEPOSITS IN AD AND AGING	9/1/2005	7/14/2006	NIA
7K25AG022048-04	QUANTITATIVE IMAGING OF AMYLOID DEPOSITS IN AD AND AGING	9/1/2006	8/31/2007	NIA
5K25AG022048-05	QUANTITATIVE IMAGING OF AMYLOID DEPOSITS IN AD AND AGING	9/1/2007	8/31/2008	NIA

Why the Wang Grants are Related to the Inventions

The abstracts given for the grants are as follows:

The Abstract for the Wang Amyloid Grants listed in Table 11

1K25AG022048-01A1, 7K25AG022048-02, 5K25AG022048-03, 7K25AG022048-04 and 5K25AG022048-05

DESCRIPTION (provided by applicant): In this application for a Mentored Quantitative Research Career Development Award (K25), the candidate's research and career development plans are described. The project is designed to customize the educational and research activities for the candidate to achieve two major goals. The immediate goal is for the candidate to continue his research in **amyloid imaging** in **Alzheimer's disease** and aging. The long-term goal is for the candidate to acquire advanced biomedical research skills and develop as an independent researcher in aging-related biomedical imaging. To achieve these goals, the candidate will obtain further trainings in neuroscience, biostatistics, pharmacology, and pharmacokinetics as well as in responsible conduct of biomedical and clinical research. He will also acquire related knowledge through journal clubs, research seminars, lectures, and conferences, and through interaction with other investigators and trainees. The practical skills in biomedical imaging will primarily be obtained through the proposed microPET studies under the guidance of Drs. Mathis and Klunk at the University of Pittsburgh. In this proposed research, the candidate plans to use microPET to evaluate amyloid-imaging agents in transgenic mice models of **amyloid deposition**. This will allow us for the first time to evaluate the in vivo binding specificity and pharmacokinetic profiles of lead compounds in a CNS model that mimics the future human studies. Therefore, this project will satisfy the following specific aims: 1) rationally design and synthesize a selected array of amyloid-binding agents; 2) evaluate the new compounds for in vitro binding affinity and specificity for amyloid deposits; 3) evaluate selected compounds in ex vivo studies of brain entry, crearance; and metabolism in normal control mice with no amyloid deposits in the brain; 4) use microPET to assess the in vivo properties of selected compounds in amyloid-containing transgenic mouse models to determine **in vivo** binding specificity and detailed pharmacokinetic profiles. The overall goal of our research is to identify potent, selective, and brain permeable amyloid probes suitable for in vivo human studies.

The patents listed above in Table 2 provide several key terms/words that appear to be the subject matter of the grants listed in Table 11, including, to mention a few:

- These facts have little implications for **amyloid imaging** studies in which an extremely minute amount of the high specific activity radiolabelled dye would be directly injected into the blood stream. (PAGE 4, PATENT 7,351,401)
- The disease states or maladies include but are not limited to **Alzheimer's Disease**, familial **Alzheimer's Disease**, Down's Syndrome and homozygotes for the apolipoprotein E4 allele. (ABSTRACT, PATENT 7270800)
- **In Vivo** Baboon Imaging Studies (PAGE 17, PATENT 8,236,282)
- In allowing the temporal sequence of **amyloid deposition** to be followed, the inventive compound may further be used to correlate **amyloid deposition** with the onset of clinical symptoms associated with a disease, disorder or condition. (PAGE 5, PATENT 8,236,282)
- This study reflects **brain entry** and clearance from normal brain tissue. (PAGE 16, PATENT 8,236,282)

The Vizamyl Prices

Vizamyl injection is available in 10 or 30 mL multi-dose glass vial at a strength of 150 MBq/mL (4.05 mCi/mL). The price of 1 vial (5 mCi) is approximately $28,000.[10]

Requested Remedies for Non-disclosure

The Bayh-Dole Act and federal regulations and guidelines obligate contractors to disclose government rights in subject inventions, including via: (1) a requirement to disclose within a reasonable time that federal funding contributed to a subject invention; (2) contractual requirements for disclosure; and (3) required language to be inserted in patent applications and the patents, stating the role of federal funding and the government's rights.

After establishing a failure by the patent holder to disclose the federal funding, an agency may choose to require the patent holders to provide a disclosure to iEdison and to submit a Certificate of Correction to the United States Patent and Trademark (UPSPTO). The agency also has consequential remedies. In particular, a failure to disclose subject inventions pursuant to 35 U.S.C. § 202(c)(1) permits the federal government to "receive title to any subject invention not disclosed to it within such time."

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[10] https://www.rxgo.com/drug/vizamyl-coupon

The disclosure itself is an acknowledgement that the federal government has certain rights in the patents, and that the patent holder has certain obligations. When federal funding is involved, the patent owner has an obligation to manufacture the invention substantially within the United States and to make the invention “available to the public on reasonable terms.” The federal government possesses a worldwide royalty-free right to use the patent, and may grant a compulsory license to the patent under the Bayh-Dole march-In provisions of 35 U.S.C. § 203(a).

The failure to make a timely disclosure of the federal funding should be seen as an attempt to evade these responsibilities and as a denial of the government’s rights in the invention.

KEI recommends that the federal government take title to the invention, since the lesser remedy of requiring late disclosure has not, in the past, provided an adequate incentive for patent holders to comply with the disclosure obligations.

For a more detailed discussion of the specific statutory, regulatory and contractual obligations to disclose federal funding in patented inventions, and the remedies when funding is not disclosed, see: KEI Briefing Note 2018:1.

ANNEX 1: Select News Reports and Other Background on Vizamyl

About Alzheimer’s disease. Alzheimer’s Association.

2014. Scott Lerman. GE Healthcare Announces European Union Approval of VIZAMYL™ (Flutemetamol (18F) Solution for Injection) for PET Imaging of Beta Amyloid Plaque in Suspected Alzheimer’s Disease. *Business Wire*. September 1, 2014.

2015. Lauren Dubinsky. GE’s Vizamyl improves diagnostic confidence for early-onset dementia. *DOTmed*. July 22, 2015.

ANNEX 2: NIH Grants to the University of Pittsburgh with William E. Klunk Listed as Principal Investigator, with Search Term “Amyloid”

The search term for NIH RePORTER database: "Text Search: amyloid (and); Search in: Projects, AdminIC: All; Principal Investigator / Project Leader: Klunk; William; Fiscal Year: All Fiscal Years."

Project Number	Project Title	Fiscal Year	FY Cost
1F32AG005443-01	Molecular Probes For Alzheimer Beta-amyloid Protein	1988	$27,000
5F32AG005443-02	Molecular Probes For Alzheimer Beta-amyloid Protein	1989	$31,750
1K02AG001039-01A1	Pet Imaging Probes For Amyloid In Alzheimers And Aging	2001	$97,686
1R01AG020226-01	Pet Tracers To Monitor Vaccine And Immune Therapy For AD	2001	$366,936
5K02AG001039-02	Pet Imaging Probes For Amyloid In Alzheimers And Aging	2002	$97,686
5R01AG020226-02	Pet Tracers To Monitor Vaccine And Immune Therapy For AD	2002	$353,050
5K02AG001039-03	Pet Imaging Probes For Amyloid In Alzheimers And Aging	2003	$97,686
5R01AG020226-03	Pet Tracers To Monitor Vaccine And Immune Therapy For AD	2003	$353,050
5R01AG020226-04	Pet Tracers To Monitor Vaccine And Immune Therapy For AD	2004	$353,050
5K02AG001039-04	Pet Imaging Probes For Amyloid In Alzheimers And Aging	2004	$97,686
5K02AG001039-05	Pet Imaging Probes For Amyloid In Alzheimers And Aging	2005	$97,686
1R37AG025516-01	Amyloid Pathology And Cognition In Normal Elderly	2005	$430,155
1P01AG025204-01	Cross-sectional Assessment Of In Vivo Amyloid In Mci And AD	2005	$157,425
2P50AG005133-22	Natural History Of Amyloid Deposition In Familial AD	2005	$185,625
5R01AG020226-05	Pet Tracers To Monitor Vaccine And Immune Therapy For AD	2005	$353,050
5P50AG005133-23	Natural History Of Amyloid Deposition In Familial AD	2006	$128,746
5P01AG025204-02	Cross-sectional Assessment Of In Vivo Amyloid In Mci And AD	2006	$172,602
1U01AG028526-01	Amyloid-lowering Small Molecule Ab-binding Agents In AD	2006	$459,078
5R37AG025516-02	Amyloid Pathology And Cognition In Normal Elderly	2006	$459,594
5P01AG025204-03	Cross-sectional Assessment Of In Vivo Amyloid In Mci And AD	2007	$298,271
5U01AG028526-02	Amyloid-lowering Small Molecule Ab-binding Agents In AD	2007	$450,738
5P50AG005133-24	Natural History Of Amyloid Deposition In Familial Alzheimers Disease	2007	$214,077
5R37AG025516-03	Amyloid Pathology And Cognition In Normal Elderly	2007	$459,409
5R37AG025516-04	Amyloid Pathology And Cognition In Normal Elderly	2008	$449,361
5P50AG005133-25	Natural History Of Amyloid Deposition In Familial Alzheimers Disease	2008	$215,088
3P01AG025204-04S1	In Vivopib Pet Amyloid Imaging: Normals; Mci & Dementia	2008	$142,645
5P01AG025204-04	In Vivopib Pet Amyloid Imaging: Normals; Mci & Dementia	2008	$1,031,916
5U01AG028526-03	Amyloid-lowering Small Molecule Ab-binding Agents In AD	2008	$454,087
5P01AG025204-04	Cross-sectional Assessment Of In Vivo Amyloid In Mci And AD	2008	$259,127

5P50AG005133-26	Natural History Of Amyloid Deposition In Familial Alzheimers Disease	2009	$221,371
5P01AG025204-05	In Vivopib Pet Amyloid Imaging: Normals; Mci & Dementia	2009	$1,151,713
5U01AG028526-04	Amyloid-lowering Small Molecule Ab-binding Agents In AD	2009	$466,821
5R37AG025516-05	Amyloid Pathology And Cognition In Normal Elderly	2009	$362,933
5P01AG025204-05	Cross-sectional Assessment Of In Vivo Amyloid In Mci And AD	2009	$360,047
3R37AG025516-05S1	Amyloid Pathology And Cognition In Normal Elderly	2009	$5,000
2P01AG025204-06	Modulators Of Cognitive Transifion From Mci To AD	2010	$301,836
4R37AG025516-06	Amyloid Pathology And Cognition In Normal Elderly	2010	$473,345
2P01AG025204-06	In Vivo Pib Pet Amyloid Imaging: Normals; Mci & Dementia	2010	$1,538,583
5U01AG028526-05	Amyloid-lowering Small Molecule Ab-binding Agents In AD	2010	$504,093
5P01AG025204-07	In Vivo Pib Pet Amyloid Imaging: Normals; Mci & Dementia	2011	$1,482,584
5R37AG025516-07	Amyloid Pathology And Cognition In Normal Elderly	2011	$481,954
5P50AG005133-28	Natural History Of Amyloid Deposition Familial Ad	2011	$199,286
5P50AG005133-29	Natural History Of Amyloid Deposition Familial Ad	2012	$182,113
5P01AG025204-08	Administrative Core	2012	$126,424
5P01AG025204-08	Modulators Of Cognitive Transifion From Mci To Ad	2012	$337,923
5P01AG025204-08	Quantitative Neuropathological Correlates Of In Vivo Pib Retention	2012	$287,620
5R37AG025516-08	Amyloid Pathology And Cognition In Normal Elderly	2012	$480,423
5P01AG025204-08	In Vivo Pib Pet Amyloid Imaging: Normals; Mci & Dementia	2012	$1,420,069
5R37AG025516-09	Amyloid Pathology And Cognition In Normal Elderly	2013	$441,934
5P01AG025204-09	Modulators Of Cognitive Transifion From Mci To Ad	2013	$267,813
5P01AG025204-09	Administrative Core	2013	$113,777
5P01AG025204-09	Quantitative Neuropathological Correlates Of In Vivo Pib Retention	2013	$274,558
5P01AG025204-09	In Vivo Pib Pet Amyloid Imaging: Normals; Mci & Dementia	2013	$1,295,247
5P50AG005133-30	Natural History Of Amyloid Deposition Familial Ad	2013	$170,365
2RF1AG025516-11	Amyloid Pathology And Cognition In Normal Elderly	2014	$2,701,818
5P01AG025204-10	Administrative Core	2014	$126,259
5P01AG025204-10	Modulators Of Cognitive Transifion From Mci To Ad	2014	$175,638
5P01AG025204-10	Quantitative Neuropathological Correlates Of In Vivo Pib Retention	2014	$286,635
5P01AG025204-10	In Vivo Pib Pet Amyloid Imaging: Normals; Mci & Dementia	2014	$1,146,355
5R37AG025516-10	Amyloid Pathology And Cognition In Normal Elderly	2014	$227,443
5P50AG005133-31	Natural History Of Amyloid Deposition Familial Ad	2014	$182,280

1U01AG051406-01	Neurodegeneration In Aging Down Syndrome (niad): A Longitudinal Study Of Cognition And Biomarkers Of Alzheimer's Disease	2015	$3,656,559
2P01AG025204-11A1	Imaging Pathophysiology In Aging And Neurodegeneration	2016	$1,998,101
3RF1AG025516-11S1	Amyloid Pathology And Cognition In Normal Elderly	2016	$782,946
5U01AG051406-02	Neurodegeneration In Aging Down Syndrome (niad): A Longitudinal Study Of Cognition And Biomarkers Of Alzheimer's Disease	2016	$3,556,865
3U01AG051406-03S1	Neurodegeneration In Aging Down Syndrome (niad): A Longitudinal Study Of Cognition And Biomarkers Of Alzheimer's Disease	2017	$158,939
5P01AG025204-12	Imaging Pathophysiology In Aging And Neurodegeneration	2017	$2,020,576
3U01AG051406-03S2	Neurodegeneration In Aging Down Syndrome (niad): A Longitudinal Study Of Cognition And Biomarkers Of Alzheimer's Disease	2017	$163,334
5U01AG051406-03	Neurodegeneration In Aging Down Syndrome (niad): A Longitudinal Study Of Cognition And Biomarkers Of Alzheimer's Disease	2017	$3,623,562

ANNEX 3: Eighteen Patents Assigned to the University of Pittsburgh that List William E. Klunk as the Inventor

Note: only one patent disclosed federal funding.

Patent Number	Title
9,833,458	Thioflavin derivatives for use in the antemortem diagnosis of Alzheimer's disease and in vivo imaging and prevention of amyloid deposition
9,808,541	Thioflavin derivatives for use in antemortem diagnosis of Alzheimer's disease and in vivo imaging and prevention of amyloid deposition
9,134,328	Methods of using benzothiazole derivative compounds and compositions
8,911,707	Thioflavin derivatives for use in antemortem diagnosis of alzheimer's disease and in vivo imaging and prevention of amyloid deposition
8,691,185	Benzothiazole derivative compounds, compositions and uses
8,580,229	Amyloid imaging as a surrogate marker for efficacy of anti-amyloid therapies

8,404,213	Thioflavin derivatives for use in antemortem diagnosis of Alzheimer's disease and in vivo imaging and prevention of amyloid deposition
8,343,457	Amyloid imaging as a surrogate marker for efficacy of anti-amyloid therapies
8,236,282	Benzothiazole derivative compounds, compositions and uses
8,147,798	Amyloid imaging as a surrogate marker for efficacy of anti-amyloid therapies
8,138,360	Isotopically-labeled benzofuran compounds as imaging agents for amyloidogenic proteins
7,854,920	Thioflavin derivatives for use in antemortem diagnosis of alzheimer's disease and in vivo imaging and prevention of amyloid deposition
7,351,401	Thioflavin derivatives for use in the antemortem diagnosis of Alzheimers disease and in vivo imaging and prevention of amyloid deposition
7,270,800	Thioflavin derivatives for use in antemortem diagnosis of Alzheimer's disease and in vivo imaging and prevention of amyloid deposition
6,417,178	Amyloid binding nitrogen-linked compounds for the antemortem diagnosis of alzheimer's disease, in vivo imaging and prevention of amyloid deposits
6,168,776	Alkyl, alkenyl and alkynyl Chrysamine G derivatives for the antemortem diagnosis of Alzheimer's disease and in vivo imaging and prevention of amyloid deposition
6,133,259	Alkyl, alkenyl and alkynyl chrysamine G derivatives for inhibition of cell degeneration and toxicity associated with amyloid deposition
6,1144,175	Compound for the antemortem diagnosis of Alzheimer's Disease and in vivo imaging and prevention of amyloid deposition

ANNEX 4: NIH Grants to the University of Pittsburgh with Chester A. Mathis Listed as Principal Investigator, with Search Term “Amyloid”

The search term for NIH RePORTER database: “Text Search: amyloid (and); Search in: Projects, AdminIC: All; Principal Investigator / Project Leader: Mathis; Chester; Fiscal Year: All Fiscal Years.”

Project Number	Project Title	Agency	FY	FY Cost
1R01AG018402-01A1	Amyloid Imaging Agents For Positron Emission Tomography	NIA	2001	$350,525
5R01AG018402-02	Amyloid Imaging Agents For Positron Emission Tomography	NIA	2002	$349,224
5R01AG018402-03	Amyloid Imaging Agents For Positron Emission Tomography	NIA	2003	$347,922
5R01AG018402-04	Amyloid Imaging Agents For Positron Emission Tomography	NIA	2004	$346,619
2R01AG018402-05	Amyloid Imaging Agents For Position Emission Tomography	NIA	2007	$339,851
5R01AG018402-06	Amyloid Imaging Agents For Position Emission Tomography	NIA	2008	$376,408
5R01AG018402-07	Amyloid Imaging Agents For Position Emission Tomography	NIA	2009	$394,437
5R01AG018402-08	Amyloid Imaging Agents For Position Emission Tomography	NIA	2010	$357,159
1S10RR028324-01	Siemens Eclipse Hp Cyclotron For Pet Imaging Research	NCRR	2010	$2,688,777
2P50AG005133-32	Project 2: Pet Imaging Of Tau In Elderly Controls; Mci; And Ad	NIA	2015	$137,119
5P50AG005133-33	Project 2: Pet Imaging Of Tau In Elderly Controls; Mci; And Ad	NIA	2016	$137,119
5P50AG005133-34	Project 2: Pet Imaging Of Tau In Elderly Controls; Mci; And Ad	NIA	2017	$137,119

Bayh-Dole Obligations to Disclose Federal Funding in Patented Inventions

KEI Briefing Note: 2018:1. Andrew Goldman. Revised March 16, 2018

Legal, Regulatory, and Contractual Obligations[1]

The Bayh-Dole Act and federal regulations and guidelines make clear several obligations for contractors in the disclosure of government rights in subject inventions, including: (1) a requirement to disclose that federal funding contributed to an invention; (2) contractual requirements for disclosure; and (3) required language to be inserted in patent applications and the patents, stating the role of federal funding and the government's rights.

First, contractors are required to disclose subject inventions discovered with federal funding in a timely manner and with sufficient detail to describe the invention.

Under 35 U.S.C. § 202(c)(1), any contractor that receives funding from the federal government is required to "disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters."[2]

Under 37 C.F.R. § 401.3(a), each federal funding agreement shall contain the "standard patent rights clause" found at 37 C.F.R. § 401.14(a), barring specific circumstances and exceptions.[3] Subsection (c)(1) of the patent rights clause outlines the disclosure requirements, including a two month time limit on the disclosure of patents and a requirement that the disclosure have sufficient detail:[4]

37 C.F.R. § 401.14(a)(c)(1)

(c) Invention Disclosure, Election of Title and Filing of Patent Application by *Contractor*

(1) The *contractor* will disclose each subject invention to the *Federal Agency* within two months after the inventor discloses it in writing to *contractor* personnel responsible for patent matters. The disclosure to the *agency* shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or

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[1] See: https://www.keionline.org/bayh-dole/failure-to-disclose

[2] The statute defines a "subject invention" at 35 U.S.C. § 201(e) as "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement," and defines a contractor at 35 U.S.C. § 201(c) as "any person, small business firm, or nonprofit organization that is party to a funding agreement."

[3] The exceptions do not contain reference to the disclosure requirements.

[4] Italics in original.

> electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the *agency*, the *Contractor* will promptly notify the *agency* of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the *contractor*.
>
> …
>
> (4) Requests for extension of the time for disclosure, election, and filing under subparagraphs (1), (2), and (3) may, at the discretion of the *agency*, be granted.

Second, in implementing this regulation, agencies may require disclosure through documentation and/or via iEdison, an online electronic system for reporting inventions and patents discovered under federal grants, or via other documents to be submitted.[5] iEdison is run by the National Institutes of Health (NIH), but is used by a wide variety of agencies, including:

Agency for Health Care Research and Quality (AHRQ)
Agricultural Research Service (ARS)
Agency for Toxic Substances and Disease Registry (ATSDR)
Air Force Office of Scientific Research (AFOSR)
Air Force Research Laboratory Information Directorate (AFRL/RI)
Air Force Materiel Command Legal Office (AFMCLO/JAZ)
Army Medical Research and Materiel Command (ARMY/MRMC)
Army Natick Soldier Systems Center (ARMY/SSC)
Army Research Laboratory (ARMY/ARL)
Army Research Office (ARMY/ARO)
Army Space and Missile Defense Command (ARMY/SMDC)
Centers for Disease Control and Prevention (CDC)
Defense Advanced Research Projects Agency (DARPA)
Defense Microelectronics Activity (DMEA)
Defense Threat Reduction Agency (DTRA)
Department of Energy (DOE)
Department of Homeland Security
Science and Technology Directorate (DHS/S&T)
Department of Transportation (DOT)
Economic Development Administration (EDA)
Environmental Protection Agency (EPA)
Food and Drug Administration (FDA)
Indian Health Service (IHS)

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[5] iEdison.gov

International Trade Administration (ITA)
National Institute of Food and Agriculture (NIFA)
National Institutes of Health (NIH)
National Institute of Standards and Technology (NIST)
National Oceanic and Atmospheric Administration (NOAA)
National Science Foundation (NSF)
Nuclear Regulatory Commission (NRC)
Office of Naval Research (ONR)
U.S. Agency for International Development (USAID)
United States Forest Service (USFS)

iEdison was created in 1995 in the wake of findings by the Office of Inspector General of the Department of Health and Human Services that the NIH was not sufficiently overseeing and monitoring compliance with Bayh-Dole requirements, including disclosure.[6]

By way of example of how agencies require disclosure, the NIH requires contractors to disclose subject inventions via iEdison, as well as via HHS Form 568, entitled, “Final Invention Statement and Certification (For Grant or Award),” available at: https://grants.nih.gov/grants/hhs568.pdf.

The NIH specifies the required information on a FAQ related to the use of iEdison, and also notes that contractors should disclose the subject invention even if they have, in the past, failed to report the invention within the two month period:[7]

5. What information is required to report a subject invention?

The invention disclosure must include the following information:

-Either the EIR Number, Invention Docket Number, or both.

-Invention Title

-Names of all of the inventors and the institutions with which they are associated

-Invention Report Date

-Description of the Invention that must meet the standards set forth per 37 CFR Sec. 401.14 (a)(c)(1):

> **“. . . be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of**

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[6] https://oig.hhs.gov/oei/reports/oei-03-91-00930.pdf
[7] Available at: https://era.nih.gov/iedison/iedison_faqs.cfm#VIII5 (accessed Jan. 6, 2017).

the invention."37 C.F.R. 401.14(a)(c)(1)"

-Primary Funding Agency

-All funding agreement numbers and names of the funding agencies

- Any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure

9. If I upload a patent application, can that patent application satisfy the Invention Disclosure Report requirement?

Yes, so long as the EIR Number or Invention Docket Number is included on the submission, the patent record containing the patent/patent application number has been reported in iEdison, and you upload proof that the patent application was filed with the USPTO, e.g., a USPTO submission receipt.

10. What should a grantee/contractor do if a subject invention hasn't been reported to the awarding agency within the required 2 month period?
Always report the invention, even if it is late. The invention report date should be the date the inventor notified the awardee institution of the subject invention. Provide an explanation in the "Explanatory Notes" section of the invention record.

On February 17, 2016, NIH issued a notice entitled "Reminder: All Subject Inventions Must Be Reported on the HHS 568 - Final Invention Statement and Certification (For Grant or Award) and in iEdison." The notice explained that failure to disclose the subject invention via both iEdison and Form 568 could result in the loss of rights in the invention.[8]

Finally, under 35 U.S.C. § 202(c)(6) and 37 C.F.R. § 1.77(b)(3), contractors are required to state within the patent application that the federal government contributed funding to support the discovery of the invention and that the government retains certain rights:

35 U.S.C. § 202(c)(6)
(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

…

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[8] National Institutes of Health, Reminder: All Subject Inventions Must Be Reported on the HHS 568 - Final Invention Statement and Certification (For Grant or Award) and in iEdison, NOT-OD-16-066 (Feb. 17, 2016), NIH Guide Notice, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-066.html.

> (6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.
>
> **35 C.F.R. § 1.77(b)(3)**
>
> (b) The specification should include the following sections in order:
>
> …
>
> (3) Statement regarding federally sponsored research or development.

The Manual of Patent Examining Procedure contains the following recommended language:

> “This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention.”[9]

Remedies for Non-Disclosure

Non-disclosure Permits the Federal Government to Receive Title to the Invention

Failure to disclose subject inventions pursuant to 35 U.S.C. § 202(c)(1) permits the Federal Government to “**receive title to any subject invention not disclosed to it within such time**” (emphasis added).

The patent rights clause at 37 C.F.R. § 401.14(a) specifies this right to claim title in subsection (d):

> **37 C.F.R. § 401.14(a)**
> (d) Conditions when the Government May Obtain Title
>
> The contractor will convey to the Federal agency, upon written request, title to any subject invention—
> (1) If the contractor fails to disclose or elect title to the subject invention within the times specified in (c), above, or elects not to retain title; provided that the agency may only request title within 60 days after learning of the failure of the contractor to disclose or elect within the specified times.

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[9] MPEP (9th ed. Rev. 07.2015, Nov. 2015), § 310.

...

In the past, the Federal Government has utilized its authority to claim title in subject inventions that have not been properly disclosed, as in the case of *Campbell Plastics Engineering & Mfg., Inc. v. Brownlee*, 389 F.3d 1243 (Fed. Cir. 2004) (finding that federal government claim of title in invention was legitimate under federal acquisition regulations and supported by the Bayh Dole Act where disclosure submissions were “piecemeal” and violated the contractual agreement with the government); *see also Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1352-53 (Fed. Cir. 2007) (“Critically, *Campbell Plastics* holds that a Bayh–Dole violation grants the government *discretionary* authority to take title. . . . When a violation occurs, the government can choose to take action; thus, title to the patent may be voidable.”).

In *Campbell Plastics*, the court found that the contract was clear and unambiguous, but moreover the government’s claim to title was “buttressed by the policy considerations behind the Bayh Dole Act.” *Id.* at 1248. These include, specifically under 35 U.S.C. § 200, the need “to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions.”

Correction of the Patent Will Establish Other Enforceable Rights For the Federal Government

Even if the Government permits the continued use of its invention, forcing a correction to the patent will create enforceable obligations and rights designed to protect the public interest. These rights can be used as leverage to force concessions in pricing.

Local Manufacturing

Under 35 U.S.C. § 204, for example, there is a requirement (waivable in individual cases) that the subject invention be manufactured substantially in the United States.[10]

35 U.S.C. § 204

Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

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[10] See also the patents rights clause regarding preference for United States industry at 37 C.F.R. § 401.14(a)(i).

Practical Application

Government rights in a subject invention also implicates the requirement repeated in numerous sections of the Bayh-Dole Act that there be “practical application” of the invention, including once in 35 U.S.C. § 203 on march-in rights, and nine times in 35 U.S.C. § 209 on licensing federally-owned inventions. “Practical application” is defined under 35 U.S.C. § 201(f) to mean “manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized **and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms**.” (Emphasis added.)

The phrase “available to the public on reasonable terms” to is a statutory obligation in the Bayh-Dole Act that only has meaning if the invention is available at a reasonable price, and while the NIH has been loath to enforce this requirement, the Congress is increasingly focused on a practical implementation of such an obligation. For example, in 2017, the Senate Armed Services Committee adopted a directive in a committee report to require enforcement of this obligation when the prices of a medical technology were higher in the United States than the median price charged in seven countries with large economies with at least 50 percent of U.S. per capita income.[11] There is also U.S. and international case law, as well as statutes in the U.K. and South Africa, defining the phrase “reasonable terms” to include the price of a product of service.[12]

March-In Rights and the Royalty-Free Right

Under 35 U.S.C. § 203(a), the government may require the grant of a license to a third party, or may grant such a license itself, if any of four conditions are met, including the obligation of practical application:

35 U.S.C. § 203

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[11] 115TH Congress, 1st Session, 2017, Senate Report 115–125. National Defense Authorization Act for Fiscal Year 2018. Report to accompany S. 1519, page 173.

[12] See KEI 10 March 2017 Comments on Army Exclusive License on Zika Virus Vaccine Patents to Sanofi, available at https://www.keionline.org/wp-content/uploads/2017/03/KEI-March_10_2017-3rd-Comments-Zika.pdf.

(a)With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such—

(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
(2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
(3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
(4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

The government also retains a perpetual non-exclusive royalty-free license in the invention, written into any funding agreement under 35 U.S.C. § 202(c)(4), and again iterated as a required term and condition for any license of a federally-owned invention under § 209(d)(1). The royalty-free right, as opposed to the march-in rights, has no precondition and can be used at any time, for any reason.

35 U.S.C. § 202

...

(c)Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

...

(4)

With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: Provided, That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreement relating to weapons development and production.

35 U.S.C. § 209
...
(d)Terms and Conditions.—Any licenses granted under section 207(a)(2) shall contain such terms and conditions as the granting agency considers appropriate, and shall include provisions—
(1)
retaining a nontransferable, irrevocable, paid-up license for any Federal agency to practice the invention or have the invention practiced throughout the world by or on behalf of the Government of the United States;
...

Both of these rights provide significant leverage to the United States, as they could be used to allow affordable competition. Even the viable threat of use of either of these rights might be sufficient to prompt price reductions or other concessions increasing access while decreasing price.

In some cases there may be more than one patent in a particular medicine, and not all patents may have government rights. In the event that there is at least one patent with government rights, the government could potentially use the royalty-free right in conjunction with the government use provision of 28 U.S.C. § 1498. While § 1498 has been used many times by the military, interest in using the government use law alone on medical technologies has been complicated by uncertainty as to the extent of compensation owed.[13] Using the royalty-free right and § 1498 together would lessen the amount of compensation owed to the patent holder.

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[13] See, *e.g.* May 12, 2015 letter from Senator Bernard Sanders to Secretary of the US Department of Veterans Affairs, Robert McDonald. https://www.keionline.org/wp-content/uploads/2015/05/12may2015-Sanders-McDonald-Veterans-1498.pdf; and https://www.keionline.org/22842.

From: Jambou, Robert (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FF42A9FA39824980AA9E36AF49E56CBC-JAMBOUR]
Sent: 8/7/2018 4:44:55 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: KEI FOIA - Communications to NIH FOIA Officer
Attachments: RE: FOIA 45260 for OCPL/FOIA office

Hi Mark,

I have compared redactions we have requested with those proposed by NHLBI. b5

b5

I will review all files to make sure that everything looks right.

I am attaching the e-mail from NHLBI with instructions for me and communications going to the NIH FOIA Officer. Let me know if you have any questions or concerns about these.

Best,

Bob J.

From: Manheim, Marianne (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DA86306719544197849B5A678839C0F5-MANHEIMMJ]
Sent: 8/7/2018 12:54:38 PM
To: Jambou, Robert (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff42a9fa39824980aa9e36af49e56cbc-jambour]
Subject: RE: FOIA 45260 for OCPL/FOIA office
Attachments: Partial Denial Memo NIH.Docx; Program Statement 45260_OSP.docx

Hi Bob,

I've gone through and added the redactions. b5

b5

Additionally, I have drafted the attached program statement that will accompany whatever we agree to send forward. Please take a look at that and let me know if you have any changes. Once we are in agreement, please sign by your name. I am attaching the draft request for partial denial that our office sends to OD, too, so you can see that one as well.

Thanks,
Marianne

From: Jambou, Robert (NIH/OD) [E]
Sent: Tuesday, July 31, 2018 4:38 PM
To: Manheim, Marianne (NIH/NHLBI) [E] <marianne.manheim@nih.gov>
Subject: RE: FOIA 45260 for OCPL/FOIA office

OK, I see:

b5

Would you like me to double check and fix this?

Apologies,

Bob J.

From: Manheim, Marianne (NIH/NHLBI) [E]
Sent: Tuesday, July 31, 2018 4:23 PM
To: Jambou, Robert (NIH/OD) [E] <jambour@od.nih.gov>
Subject: RE: FOIA 45260 for OCPL/FOIA office

In the June set.

From: Jambou, Robert (NIH/OD) [E]
Sent: Tuesday, July 31, 2018 3:53 PM
To: Manheim, Marianne (NIH/NHLBI) [E] <marianne.manheim@nih.gov>
Subject: RE: FOIA 45260 for OCPL/FOIA office

Not sure.

b5

Bob J.

From: Manheim, Marianne (NIH/NHLBI) [E]
Sent: Tuesday, July 31, 2018 3:42 PM
To: Jambou, Robert (NIH/OD) [E] <jambour@od.nih.gov>
Subject: RE: FOIA 45260 for OCPL/FOIA office

Thanks. One more question. b5
b5

From: Jambou, Robert (NIH/OD) [E]
Sent: Tuesday, July 31, 2018 3:40 PM
To: Manheim, Marianne (NIH/NHLBI) [E] <marianne.manheim@nih.gov>
Subject: RE: FOIA 45260 for OCPL/FOIA office

No, I did not, but:
Gorka (sent KEI "an are you still interested letter" and they responded in the affirmative...
See attached.

Bob J.

From: Manheim, Marianne (NIH/NHLBI) [E]
Sent: Tuesday, July 31, 2018 7:30 AM
To: Jambou, Robert (NIH/OD) [E] <jambour@od.nih.gov>
Subject: RE: FOIA 45260 for OCPL/FOIA office

Did you, by chance, send an interim letter at the beginning?

From: Jambou, Robert (NIH/OD) [E]
Sent: Monday, July 30, 2018 1:36 PM
To: NHLBI FOIA REQUEST (NIH/NHLBI) <nhlbifoiarequest@nhlbi.nih.gov>
Cc: Manheim, Marianne (NIH/NHLBI) [E] <marianne.manheim@nih.gov>
Subject: FOIA 45260 for OCPL/FOIA office

Hi Marianne,

I am about to send you records for FOIA 45260 (Goldman KEI) using SEFT. The package consists of 10 files (5 with mark ups and 5 without mark ups). The files are sorted in reverse chronological order and by month, starting end of June, though May, April, March and through beginning of January 2018 (includes February). The files have been reviewed both by myself and subsequently by OD/OSP (Mark Rohrbaugh – Director of technology transfer OSP.

The incoming request is attached

About this FOIA request:

A non-profit organization, Knowledge Ecology International (KEI) petitioned NIH in January 2016 to exercise its “March-In” rights under Bayh-Dole to force the lowering in price of a prostate cancer drug (Xtandi, aka enzalutamide) that was developed using NIH funds (i.e. taxpayer funds) and marketed in the US by Astellas Pharma. While there have been other examples of requests to “March-In”, NIH has never done so. The records responsive to this request involved a letter from Congress, a letter written by NIH for then Secretary Burwell to sign in response to the congressional communication, and numerous internal discussions (including exchanges with DOD) on how to proceed with the NIH decision to not exercise its “March-In” rights.

b5

Thanks for helping me out with these massive responses.

Bob J.

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
Office of Science Policy
FOIA/PA Office, RKL 1, Suite 6054
6705 Rockledge Dr. MSC 7957
Bethesda MD 20892-7957

TO: NIH FOIA Office, Attn: Gorka Garcia-Malene, Bldg. 31, Room 5B35
FROM: Marianne Manheim, NHLBI FOIA Office, Rockledge 1, Room 6176 b6
DATE: August 7, 2018
SUBJECT: NIH FOIA Case Number 45260 – Request for Partial Denial

Background: A non-profit organization, Knowledge Ecology International (KEI) petitioned NIH in January 2016 to exercise its "March-In" rights under Bayh-Dole to force the lowering in price of a prostate cancer drug (Xtandi, aka enzalutamide) that was developed using NIH funds (i.e. taxpayer funds) and marketed in the US by Astellas Pharma. While there have been other examples of requests to "March-In", NIH has never done so.

Request: On June 29, 2016, Andrew S Goldman, Knowledge Ecology International, submitted a FOIA request to the National Instituted of Health regarding the petition submitted by KEI and the Union or Affordable Cancer Treatment in January 2016 that requested that the NIH use its rights in patents under the Bayh Dole Act for the prostate cancer drug enzalutamide, marketed in the U.S. by Astellas Pharma as Xtandi. Specifically, KEI requested all documents, correspondence, and notes that were generated internally or may have been submitted or sent to any NIH office, regarding the above petition, by: other offices, institutes, or components of the NIH; the US Department of Health and Human Services and any other federal departments or agencies; or non-governmental persons or entities. Period of request was Jan. 14, 2016 to present. NIH determined that NIH's Office of Science Policy (OSP) had responsive documents and tasked the request to OSP on July 7, 2016 for direct reply. OSP conducted a search for all responsive records and provided the documents to NHLBI Service Center on July 30, 2018. The correspondence spans the time period of January 14, 2016 through the end of June 2016, when the final decision was made. OSP located 1,176 pages that are responsive to the request. The files have been reviewed both by Dr. Robert Jambou and subsequently by OD/OSP (Mark Rohrbaugh – Director of technology transfer OSP). We recommend that b5 b5

The records responsive to this request involved a letter from Congress, a letter written by NIH for then Secretary Burwell to sign in response to the congressional communication, and numerous internal discussions (including exchanges with DOD) on how to proceed with the NIH decision to not exercise its "March-In" rights.

We reviewed the emails and determined that b5

b5

b5

b5

Based on the fee category, time passed, and electronic release of documents, no fees have been assessed, as they fall below the minimum.

Enclosures:
Opaque redacted documents
Translucent redacted documents
Signed program statement
Emails with the requester regarding unresponsive documents
Final response letter from NIAAA
Interim letter
Original request letter

1621 Connecticut Avenue, NW

Washington, DC 20009

Subject: NIH Case Number: 45260 for Partial Denial

starting end of June, though May, April, March and through beginning of January 2018 (includes February). .

The incoming request is attached

MEMORANDUM

TO: NIH FOIA Office, Attn: Gorka Garcia-Malene, Bldg. 31, Room 5B35

FROM: Dr. Robert Jambou, OSP

DATE: August 7, 2018

SUBJECT: Program Statement NIH FOIA Case #45260

On June 29, 2016, Andrew S Goldman, Knowledge Ecology International, submitted a FOIA request to the National Instituted of Health regarding the petition submitted by KEI and the Union or Affordable Cancer Treatment in January 2016 that requested that the NIH use its rights in patents under the Bayh Dole Act for the prostate cancer drug enzalutamide, marketed in the U.S. by Astellas Pharma as Xtandi. Specifically, KEI requested all documents, correspondence, and notes that were generated internally or may have been submitted or sent to any NIH office, regarding the above petition, by: other offices, institutes, or components of the NIH; the US Department of Health and Human Services and any other federal departments or agencies; or non-governmental persons or entities. Period of request was Jan. 14, 2016 to present. Information found within the correspondence between NIH personnel in OSP, NIH personnel, and members of the Office of General Counsel b5 b5

b5

From: Mark **b6**
Sent: 6/17/2017 8:06:47 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
CC: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: document from Mark
Attachments: WF365656 KEI Response OEROSP (002)--OGCBerkleyComments_MR2.docx

This is the document that we worked on that I am sending from the laptop

Regards,
Mark

b5

b5

From: Mowatt, Michael (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB1EF7E2E54B4164AE34814574BDA638-MMOWATT]
Sent: 11/9/2017 9:03:55 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Frisbie, Suzanne (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c402740ceaad4d4f97a8c28f16fbb349-frisbies]
Subject: RE: responses to FRNs
Attachments: Response to KTreanor DRAFT 171106_AFP MRM 171109.docx

b5

Interested in your thoughts. Also providing my response to Amy's edits. I'll also distribute to the larger group.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, November 9, 2017 3:52 PM
To: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>
Cc: Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>
Subject: RE: responses to FRNs

b5

From: Mowatt, Michael (NIH/NIAID) [E]
Sent: Thursday, November 09, 2017 3:39 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>
Subject: RE: responses to FRNs

Thanks again, Mark.

b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, November 7, 2017 4:21 PM
To: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>
Subject: FW: responses to FRNs

b5

b5 See this example.

b5

b5

From: Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]
Sent: 6/21/2018 6:05:29 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]
Subject: FW: Is there any relation between Beoro Therapeutics and Roche?

Good afternoon Mark,

I recently received this additional e-mail from KEI below. How would you like us to respond?

Thanks,
Dave

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
Rockville, MD 20850-9702 (Overnight/express mail)
Phone (Main Office): 240-276-5530
Phone (direct): (240) 276-6467
Fax: 240-276-5504

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From: Luis Gil Abinader [mailto:luis.gil.abinader@keionline.org]
Sent: Thursday, June 21, 2018 12:15 PM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Cc: Andrew S. Goldman <andrew.goldman@keionline.org>; Jamie Love <james.love@keionline.org>
Subject: Is there any relation between Beoro Therapeutics and Roche?

Hi David,

I'm writing on behalf of Knowledge Ecology International (KEI). As you are aware, we intend to file comments concerning the prospective grant of an exclusive license to Beoro Therapeutics.

Is Beoro Therapeutics a subsidiary of, or has any relation to, Roche?

We have reasons to believe Beoro or some of its employees are currently related to Roche, and this information is relevant to our ability to comment on this prospective grant of an exclusive license.

Looking forward to your reply.

Luis

From: Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]
Sent: 8/6/2018 7:32:02 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Burke, Andy (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=305e280edc664e68939d4348603f56e6-burkear]; Freel, Rose (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8ae9aab7e3249e881bb573e9a189036-freelrm]
Subject: RE: Request for Clarification on HHS' Anti-Mesothelin CAR and mAb Patent and Patent Applications

I cannot speak for Rose or Andy, b5

b5

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
Rockville, MD 20850-9702 (Overnight/express mail)
Phone (Main Office): 240-276-5530
Phone (direct): (240) 276-6467
Fax: 240-276-5504

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From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, August 06, 2018 3:27 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>; Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Cc: Gottesman, Michael (NIH/OD) [E] <gottesmm@mail.nih.gov>; McBurney, Margaret (NIH/OD) [E] <margaret.mcburney@nih.gov>; Kleinman, Joe (NIH/OD) [E] <joseph.kleinman@nih.gov>
Subject: Fwd: Request for Clarification on HHS' Anti-Mesothelin CAR and mAb Patent and Patent Applications

Did she submit a FOIA for these? b5

Sent from my iPhone

Begin forwarded message:

> **From:** Sara Elizabeth Siegler <sara@saraelizabethsiegler.mygbiz.com>
> **Date:** August 6, 2018 at 3:17:32 PM EDT
> **To:** "Lambertson, David (NIH/NCI) [E]" <david.lambertson@nih.gov>, andy.burke@nih.gov, rose.freel@nih.gov

Cc: RohrBauM@od.nih.gov, "Richard G (NIH/OD) [E]" <WyattRG@od.nih.gov>, Sara Elizabeth Siegler <sara@saraelizabethsiegler.mygbiz.com>, James Love <james.love@keionline.org>, Francis Collins <francis.collins@nih.gov>, norman.sharpless@nih.gov, rimas.orentas@seattlechildrens.org
Subject: Request for Clarification on HHS' Anti-Mesothelin CAR and mAb Patent and Patent Applications

kindly!

From: Knabb, Jim (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=535517D229E04963A2B928742CB80DA0-KNABBJR]
Sent: 4/4/2019 4:55:44 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]
Subject: Inquiry regarding FR 2019-06575 (NCI response to KEI)
Attachments: email response to CC-KEI.pdf; email response to JLove.pdf

Mark, Richard,

I've received questions from two individuals at KEI related to the FRN 2019-06575. This is for a proposed exclusive license to Senti Bio (A-112-2019). The comments/questions are fairly straightforward, so I'm proposing the attached draft email responses. b5

b5

Happy to discuss after you've had a chance to review.

Jim

Knabb, Jim (NIH/NCI) [E]

To: Claire Cassedy
Subject: RE: Inquiry regarding FR 2019-06575 - Proposed Exclusive License on CART therapies for FMS-like tyrosine kinase 3 Expressing Cancers

b5

From: Claire Cassedy <claire.cassedy@keionline.org>
Sent: Wednesday, April 3, 2019 10:42 AM
To: Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>
Subject: Inquiry regarding FR 2019-06575 - Proposed Exclusive License on CART therapies for FMS-like tyrosine kinase 3 Expressing Cancers

Dear Mr. Knabb,

I am writing in reference to the Federal Register notice (FR 2019-06575) regarding, "Prospective Grant of an Exclusive/Co-Exclusive Patent License: Development and Commercialization of Next Generation Chimeric Antigen Receptor Therapies for the Treatment of FMS-like tyrosine kinase 3 Expressing Cancers," for which you are listed as the contact for inquiries. I was hoping you could provide me with some further information regarding the status of the technologies.

1. At what stage of development are the inventions listed?
2. Has the government funded any clinical trials relevant to these technologies?
3. If the government has provided funding, how much has been spent by the government on these trials? Can you provide NCT numbers?

Thank you in advance for your assistance in this matter.

Best Regards,
Claire Cassedy

--
Claire Cassedy
Knowledge Ecology International
1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
Tel.: 1.202.332.2670

Knabb, Jim (NIH/NCI) [E]

To: James Love
Subject: RE: Senti Bio ("Senti") license

b5

From: James Love <james.love@keionline.org>
Sent: Wednesday, April 3, 2019 10:38 AM
To: Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>
Cc: Claire Cassedy <claire.cassedy@keionline.org>
Subject: Senti Bio ("Senti") license

Dear Jim Knabb,

Senti seems like a company with a very talented staff and also that has access to capital for development.

Claire may follow up with some questions on the status of the technology, as regards government funded R&D, but I wanted also to ask why the NIH is seeking a worldwide license, given the PHS licensing manual, which says the government has a commitment to access in developing countries.

1. Does the NIH intend to have requirements that these licensed technology be affordable or even accessible in developing countries, and if so, what type of requirements would do this?

2. And, if the NIH will not have provisions on access in developing countries, will the NIH consider limiting the geographic scope of the license to countries with at least 30 percent of US per capita income?

I would appreciate answers to these questions before the deadline for comments on the license.

Jamie

--
James Love. Knowledge Ecology International
U.S. Mobile +1.202.361.3040
U.S. office phone +1.202.332.2670
http://www.keionline.org
twitter.com/jamie_love

From: Thalhammer-Reyero, Cristina (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=728A39C5FFA74030A69B0C0D27DCF23B-THALHAMC]
Sent: 12/20/2017 7:56:48 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: FW: KEI and T-Cure Bioscience
Attachments: A-033-2018_PrelimDeterMemo_CTR.pdf; A-033-2018_FRNotice.pdf

Hi Mark,

Do you have any suggestions for a response to the below inquiry from KEI? b5

b5

I would appreciate any input.

Thank you and Happy Holidays!

Cristina

Cristina Thalhammer-Reyero, Ph.D., M.B.A.
Senior Licensing and Patenting Manager
Office of Technology Transfer and Development
National Heart, Lung and Blood Institute
tel: : +1-301-435-4507
ThalhamC@mail.nih.gov

This message may contain privileged and confidential information intended only for the use of the individual(s) or entity named above. If you are not the intended recipient, you are hereby notified that any use, dissemination, distribution, or copying of this message or its content is strictly prohibited. If you have received this message in error, please notify sender immediately and destroy the message without making a copy. Thank you.

From: Thalhammer-Reyero, Cristina (NIH/NHLBI) [E]
Sent: Wednesday, December 20, 2017 12:19 PM
To: Deutch, Alan (NIH/NHLBI) [E] <deutcha@nhlbi.nih.gov>
Subject: FW: T-Cure Bioscience

Thank you,
Cristina

From: James Love [mailto:james.love@keionline.org]
Sent: Wednesday, December 20, 2017 12:05 PM
To: Thalhammer-Reyero, Cristina (NIH/NHLBI) [E] <cristina.thalhammer-reyero@nih.gov>
Cc: Diane Singhroy <diane.singhroy@keionline.org>; Kim Treanor <kim.treanor@keionline.org>; Andrew S. Goldman <andrew.goldman@keionline.org>; Manon Ress <manon.ress@keionline.org>; Mundy, Alicia (Budget) <amundy@aliciamundy.com>
Subject: T-Cure Bioscience

Cristina Thalhammer-Reyero, Ph.D., MBA,
Senior Licensing and Patenting Manager,
NHLBI Office of Technology Transfer and Development,
31 Center Drive Room 4A29, MSC2479,
Bethesda, MD 20892-2479;
Telephone: +1-301-435-4507;
Fax: +1-301-594-3080;
Email: thalhamc@mail.nih.gov.

Dear Dr. Thalhammer-Reyero,

Can you tell me who T-Cure Bioscience is? The firm is about to get an exclusive for this technology:

FR Notice: 82 FR 56622
Title: Prospective Grant of Exclusive Patent License: T-Cells Transduced with HLA A11 Restricted CT-RCC HERV-E Reactive T-Cell Receptors for the Treatment of Renal Cell Carcinoma

I went to the web page an it was stock wordpress site with almost no information about the group.

https://www.t-curetherapeutic.com/mission/

Can you tell me the names of any of the principals?

Can you explain if any of the persons associated with the firm had worked at the NIH or received any funding from the NIH? Is there any CRADA involved?

Can you explain why this firm, which doesn't seem to be much of anything, should be given a monopoly on HERV-E Reactive T Cell Receptors and Methods of Use patents, for T-cell receptor based cancer immunotherapy for Renal Cell Carcinoma".

Can you tell us if this is considered a start-up license with a low royalty rate?

James Love

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, twitter.com/jamie_love

b5

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concatenated L2 peptides for the prevention of Human Papillomavirus (HPV) infection and associated diseases. Specifically excluded from the field of use are L2 based virus-like particles (VLPs), L1/L2 chimeric peptides, and L1/L2 chimeric peptide/protein based VLPs."

The subject technologies are papillomavirus L2 capsid protein based vaccines against HPV. The L2 protein is the minor papillomavirus capsid protein for papillomaviruses. It is known that antibodies to this protein can neutralize homologous infection. Furthermore, L2 proteins can induce cross-neutralizing antibodies. Specifically, epitopes at the N-terminus of L2 shared by cutaneous and mucosal types of papillomavirus types and by types that infect divergent species are broadly cross-neutralizing. These epitopes at the N-terminus of L2 can be used to elicit cross-neutralizing antibodies against different types of HPV.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 14, 2017.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2017–25744 Filed 11–28–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI SPORE V Review.

Date: February 5–6, 2018.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Washingtonian Marriott, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Mukesh Kumar, Ph.D., Scientific Review Officer, Research Program Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W618, Bethesda, MD 20892–9750, 240–276–6611, *mukesh.kumar3@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Molecular and Cellular Analysis Technologies.

Date: February 8, 2018.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W030, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Nadeem Khan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W260, Bethesda, MD 20892–9750, 240–276–5856, *nadeem.khan@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI SPORE VI Review.

Date: February 8–9, 2018.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Washingtonian Marriott, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Anita T. Tandle, Ph.D., Scientific Review Officer, Research Program Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W248, Bethesda, MD 20892–9750, 240–276–5007, *tandlea@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Quantitative Imaging.

Date: February 14, 2018.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 4W030, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Eduardo E. Chufan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W254, Bethesda, MD 20892–9750, 240–276–7975, *chufanee@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 22, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–25732 Filed 11–28–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: T-Cells Transduced with HLA A11 Restricted CT–RCC HERV–E Reactive T-Cell Receptors for the Treatment of Renal Cell Carcinoma

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: The National Heart, Lung, and Blood Institute ("NHLBI"), an institute of the National Institutes of Health; an agency within the Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to commercialize the invention(s) embodied in the intellectual property estate stated in the Summary Information section of this notice to T-Cure Bioscience, Inc. located in Thousand Oaks, California and incorporated under the laws of Delaware.

DATES: Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development on or before December 14, 2017 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Cristina Thalhammer-Reyero, Ph.D., MBA, Senior Licensing and Patenting Manager, NHLBI Office of Technology Transfer and Development, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479; Telephone: +1–301–435–4507; Fax: +1–301–594–3080; Email: *thalhamc@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The following represents the intellectual property to be licensed under the prospective agreement:

US Provisional Patent Application No. 62/357,265, filed June 30, 2016; and PCT Patent Application PCT/US2017/040449, filed June 30, 2017, "HERV–E Reactive T Cell Receptors and Methods of Use", NIH Reference No. E–120–2016/0,1.

With respect to persons who have an obligation to assign their right, title and interest to the Government of the United States of America, the patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the following: "Development and commercialization of T cell receptor based cancer immunotherapy for Renal Cell Carcinoma".

The subject technology is based on an allogeneic T cell clone isolated from a clear cell renal cell carcinoma (ccRCC) HLA–A11 patient who showed prolonged tumor regression after an allogeneic transplant. This clone was found to have tumor specific cytotoxicity, killing patient's tumor cells in vitro. The antigen recognized by this clone is an HLA–A11 restricted peptide (named CT–RCC–1) and it is encoded by a novel human endogenous retrovirus-E (named CT–RCC HERV–E) whose expression was discovered to be restricted to ccRCC, but not observed in normal tissues or other tumor types. More than 80% of ccRCC tumors express CT–RCC HERV–E provirus, which makes it an ideal target for T cell based immunotherapy. The genes for a T cell receptor (TCR) that specifically recognizes an HLA–A11 restricted CT–RCC–1 antigen were sequenced and cloned. A retroviral vector encoding this TCR as well as a truncated CD34 protein lacking the intracellular domain, which can be used to facilitate the isolation of T-cells transduced with this TCR, was created. The vector can be used to transduce and expand normal T cells from HLA–A11 patients with metastatic ccRCC with the TCR. The transduced cytotoxic T cells can then be administered to subjects to treat or inhibit metastatic kidney cancer. Kidney cancer is responsible for approximately 12,000 deaths every year in the United States alone. As with most cancer, when detected at early stages, surgical intervention is highly effective. Phase I/II clinical trials are currently being planned in patients with metastatic ccRCC using normal patient's T-cells transduced with this vector.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective Exclusive Patent License will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the NHLBI Office of Technology Transfer and Development receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

The public may file comments or objections in response to this Notice. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 16, 2017.

Cristina Thalhammer-Reyero,

Senior Licensing and Patenting Manager, Office of Technology Transfer and Development, National Heart, Lung, and Blood Institute.

[FR Doc. 2017–25743 Filed 11–28–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent Commercialization License: N6, A Novel, Broad, Highly Potent HIV-Specific Antibody

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases (NIAID), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent commercialization license to GlaxoSmithKline Intellectual Property Development Ltd (GSK) located at 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom, to practice the inventions embodied in the patent applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: Only written comments and/or applications for a license which are received by the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases on or before December 14, 2017 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent commercialization license should be directed to: Chris Kornak, Lead Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 6D, MSC 9804, Rockville, MD 20852–9804, phone number 301–496–2644, or *chris.kornak@nih.gov.*

SUPPLEMENTARY INFORMATION: The following represents the intellectual property to be licensed under the prospective agreement: HHS Reference No. E–131–2015/0–US–01, United States Provisonal Patent Application Serial No. 62/136,228, filed on 03/20/2015; HHS Reference No. E–131–2015/1–US–01, United States Provisional Patent Application Serial No. 62/250,378 filed on 11/03/2015; HHS Reference No. E–131–2015/2–PCT–01, PCT Patent Application Serial No. PCT/US2016/023145, filed on 03/18/2016; HHS Reference No. E–131–2015/2–US–07, United States Patent Application Serial No. 15/559,791, filed on 09/19/2017; HHS Reference No. E–131–2015/2–EP–05, European Patent Application Serial No. 16716979.6, filed on 10/19/2017; HHS Reference No. E–131–2015/2–CA–03, Canadian Patent Application Serial No. 2,980,005, filed on 09/15/2017; HHS Reference No. E–131–2015/2–AU–02, Australian Patent Application Serial No. 2016235541, filed on 09/08/2017; HHS Reference No. E–131–2015/2–CN–04, filing in process, HHS Reference No. E–131–2015/2–ZA–08, South African Patent Application Serial No. 2017/06155, filed on 09/11/2017; and HHS Reference No. E–131–2015/2–IN–06, Indian Patent Application

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 9/11/2017 2:36:07 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]
CC: Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]
Subject: RE: Latest version of statement on Salubris
Attachments: Response to Public Inquiries on Salubris Final 8.14.17.docx

This is for public inquiries.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Monday, September 11, 2017 10:34 AM
To: Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>
Subject: Latest version of statement on Salubris

Could you please send me your latest version of the statement you are sending folks who ask about why we plan to give an exclusive license to Salubris for the cancer cell therapy?

NCI has comments from KEI and individuals they received from the FR notice that they need to respond to.

Thanks

Mark L. Rohrbaugh, Ph.D., J.D.
Special Advisor for Technology Transfer
Director, Division of Technology Transfer and Innovation Policy
Office of Science Policy
Office of the Director
National Institutes of Health

Thank you for contacting the NIH with your questions and concerns. Many, if not most, of the technologies developed at the NIH are early stage biomedical technologies that require a great deal of further development and regulatory approval before they can be provided to patients. The time, cost and risks to develop an FDA-approved drug or vaccine are high (estimated to be at least $1 billion per drug), and only about one-tenth of a percent (0.1%) of potential drug candidates are eventually approved by the FDA. NIH supports research to identify the mechanisms of disease and the discovery of early stage technologies (an area of research generally not supported by the private sector), but relies on the private sector to bring products through the full pre-clinical and clinical process, the most expensive stages of drug development. Through the NIH's licensing program, the private sector takes early stage technologies and develops them into new treatments to benefit public health. The NIH grants exclusive licenses to incentivize companies to invest in the development of early stage NIH technologies so they can benefit public health. Without such an incentive, these early stage technologies would likely never be developed.

When a company requests an exclusive license, NIH considers carefully whether the technology should be made available on an exclusive or non-exclusive basis for that purpose. NIH's interest in licensing its inventions is public and transparent. In 2011 and 2012, NIH advertised in the Federal Register and on NIH Technology Transfer websites that the NIH inventions (several unique antibodies) were being made available for licensing. The invention can be licensed to create at least six different classes of cancer treatments, all of which were advertised. These advertisements remain active, and NIH continues to seek commercialization partners for unlicensed uses of the invention.

Prior to posting a public notice in the federal register for a proposed granting of an exclusive license, the NIH determines that the legal criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied and that a company is qualified to be granted an exclusive license to the Government's intellectual property in the fields of use as specified.

Salubris applied for an exclusive license for the development of one of these classes of drugs, which NIH is currently considering. To date, Salubris is the only company that has applied for a license for this particular aspect of the invention. Salubris has demonstrated that their researchers have significant expertise with the aspect of the inventions that they would like to license, and NIH has determined that Salubris is a strong licensing candidate.

Licenses for developing the other classes of drugs from the invention are still available for other companies to pursue. In fact, NIH has already advertised its intention to grant licenses to other companies for some of the other classes.

By taking a licensing approach that separates out the invention into classes, and by then licensing those classes separately to different companies, the NIH fosters competition in the drug market, which may lead to competitive drug pricing.

We hope that the explanation above provides some assurance that any decision NIH makes to license one of its technologies involves a lot of thought and diligence, and complies with federal laws.

From: Knabb, Jim (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=535517D229E04963A2B928742CB80DA0-KNABBJR]
Sent: 4/4/2019 5:04:42 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]
Subject: RE: Inquiry regarding FR 2019-06575 (NCI response to KEI)

OK thanks Mark, appreciate the quick response.

Jim

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, April 4, 2019 1:03 PM
To: Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: RE: Inquiry regarding FR 2019-06575 (NCI response to KEI)

Jim:

I would propose slight changes to the JL response:

b5

Regards,
Mark

Please send me your final email.

From: Knabb, Jim (NIH/NCI) [E] <jim.knabb@nih.gov>
Sent: Thursday, April 04, 2019 12:56 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: Inquiry regarding FR 2019-06575 (NCI response to KEI)

Mark, Richard,

I've received questions from two individuals at KEI related to the FRN 2019-06575. This is for a proposed exclusive license to Senti Bio (A-112-2019). The comments/questions are fairly straightforward, so I'm proposing the attached draft email responses. b5 b5

Happy to discuss after you've had a chance to review.

Jim

From: Joe Allen [jallen@allen-assoc.com]
Sent: 2/15/2017 1:51:33 AM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: KEI Compulsory Licensing Workshop

this should be a real doozie...

Here is some additional information on the Feb. 24th KEI Workshop. Hope to see you there (http://www.keionline.org/node/2717).

Workshop

History, Experiences, and Prospects of Compulsory Licensing on Medical Patents in the United States

Date: Friday February 24, 2017

Location: Kaiser Permanente Center for Total Health

700 Second St. NE (near Union Station)

Washington, DC 20002

The event will feature presentations and roundtable discussions and questions and comments from the workshop participants on several topics relating to the non-voluntary use of patents in the United States, with a focus on medical patents.

10 AM: Introduction

10:15 - 10:45

Review of all U.S. legislation proposed, enacted and/or repealed on the compulsory licensing of patents from the 19th Century to the present.

- Zack Struver, KEI

10:50 - 11:50

A discussion non-voluntary use of patents under 28 USC 1498(a), the statute that covers use of patents "by or for the United States without license of the owner."

- Amy kapczynski, Professor of Law, Yale Law School
- Robert Weissman, President, Public Citizen

11:50 AM to 12:30 PM

Lunch

12:30 PM - 1:30 PM

A discussion of the non-voluntary use of patents in court cases involving requests for permanent injunctions as a remedy to infringement, under the standards set out in the by the U.S. Supreme Court in eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006)

- Matthew Herper, Forbes
- Rachel Sachs, Associate Professor at the Washington University in St. Louis School of Law
- Andrew Goldman, Counsel for Policy and Legal Affairs, Knowledge Ecology International

1:35 PM - 3:00 PM

A discussion of the experience with the Bayh-Dole Act march-in provisions.

- Hanna Vogel, Legislative Assistant, Representative Doggett, U.S. House of Representatives
- Richard Wilder, Associate General Counsel in the Global Health Program, the Gates Foundation (May have a travel conflict)
- C. Allen Black, Jr., Ph.D., Adjunct Professor of Law, University of Pittsburgh School of Law. (Counsel for Fabrazyme march-in case).
- James Love, Knowledge Ecology International (KEI)
- Ashley Stevens, President, Focus IP Group (former President of AUTM, the Association of University Technology Managers)

3:00 PM to 3:15 PM

Break

3:15 PM to 3:45 PM A review of global norms and compulsory licensing statutes in selected industrialized countries.

- Frederick M. Abbott, Edward Ball Eminent Scholar Professor of International Law, Florida State University, College of Law
- Andrew Goldman, KEI

3:50 PM to close

A concluding discussion about the need for new statutory authority to grant compulsory licenses on patents, with references to (a) US government negotiations on prices of drugs, (b) the broader need to curb excessive prices of drugs, and (c) the role of compulsory licensing in improving access to research tools, diagnostic tests, and upstream technologies such as CRISPR Genome Editing, and for follow-on inventions.

Starting with initial comments from:

- Aaron S. Kesselheim, MD, JD, MPH, Associate Professor of Medicine at Harvard Medical School and a faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women's Hospital. (TBC)
- Amy kapczynski, Professor of Law, Yale Law School
- Rachel Sachs, Associate Professor at the Washington University in St. Louis School of Law
- James Love, KEI

- PhRMA, invited
- (May shuffle this a bit, and perhaps add a few stakeholders)

--

Joseph P. Allen
President
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60704 Rt. 26, South
Bethesda, OH 43719
(W) 740-484-1814
(c) b6
www.allen-assoc.com

From: Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]
Sent: 6/21/2018 7:05:27 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]
Subject: FW: quick question from a journalist

Hi Mark,

I also received this question from a non-KEI entity. **b5**

Thanks,

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
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Fax: 240-276-5504

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From: Silverman, Ed [mailto:ed.silverman@statnews.com]
Sent: Thursday, June 21, 2018 11:25 AM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Subject: quick question from a journalist

Hi Dave,

My name is Ed Silverman and I run the Pharmalot blog at The Boston Globe's STAT health news site, where I track the pharmaceutical industry.

A quick question about the NIH notice to provide a license to Beoro Therapeutics for a cancer drug...

https://www.federalregister.gov/documents/2018/06/07/2018-12179/prospective-grant-of-an-exclusive-patent-license-the-development-of-an-anti-bcma-immunotoxin-for-the

There's not a lot of publicly available information about Beoro and wondering why the agency chose this company. What info exists to give taxpayers confidence that such a license would be awarded to a company with the expertise and capabilities to develop the technology?

It seems one of the Beoro folks - Gerhard Niederfellner - worked at Roche. Can you confirm this and provide some insight into how this company was chosen?

Thanks
ed silverman
STAT / Pharmalot
973-493-7851
www.statnews.com/pharmalot/

From: Thalhammer-Reyero, Cristina (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=728A39C5FFA74030A69B0C0D27DCF23B-THALHAMC]
Sent: 12/20/2017 8:23:11 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Deutch, Alan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=244d755700584812af36b5e787285647-deutcha]
Subject: RE: KEI and T-Cure Bioscience

Sounds good, will do as advised.

Thank you,
Cristina

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, December 20, 2017 3:15 PM
To: Thalhammer-Reyero, Cristina (NIH/NHLBI) [E] <cristina.thalhammer-reyero@nih.gov>
Subject: RE: KEI and T-Cure Bioscience

b5

From: Thalhammer-Reyero, Cristina (NIH/NHLBI) [E]
Sent: Wednesday, December 20, 2017 2:57 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: FW: KEI and T-Cure Bioscience

Hi Mark,

Do you have any suggestions for a response to the below inquiry from KEI? b5

b5

I would appreciate any input.

Thank you and Happy Holidays!

Cristina

Cristina Thalhammer-Reyero, Ph.D., M.B.A.
Senior Licensing and Patenting Manager
Office of Technology Transfer and Development
National Heart, Lung and Blood Institute
tel: : +1-301-435-4507
ThalhamC@mail.nih.gov

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From: Thalhammer-Reyero, Cristina (NIH/NHLBI) [E]
Sent: Wednesday, December 20, 2017 12:19 PM
To: Deutch, Alan (NIH/NHLBI) [E] <deutcha@nhlbi.nih.gov>
Subject: FW: T-Cure Bioscience

Thank you,
Cristina

From: James Love [mailto:james.love@keionline.org]
Sent: Wednesday, December 20, 2017 12:05 PM
To: Thalhammer-Reyero, Cristina (NIH/NHLBI) [E] <cristina.thalhammer-reyero@nih.gov>
Cc: Diane Singhroy <diane.singhroy@keionline.org>; Kim Treanor <kim.treanor@keionline.org>; Andrew S. Goldman <andrew.goldman@keionline.org>; Manon Ress <manon.ress@keionline.org>; Mundy, Alicia (Budget) <amundy@aliciamundy.com>
Subject: T-Cure Bioscience

Cristina Thalhammer-Reyero, Ph.D., MBA,
Senior Licensing and Patenting Manager,
NHLBI Office of Technology Transfer and Development,
31 Center Drive Room 4A29, MSC2479,
Bethesda, MD 20892-2479;
Telephone: +1-301-435-4507;
Fax: +1-301-594-3080;
Email: thalhamc@mail.nih.gov.

Dear Dr. Thalhammer-Reyero,

Can you tell me who T-Cure Bioscience is? The firm is about to get an exclusive for this technology:

FR Notice: 82 FR 56622
Title: Prospective Grant of Exclusive Patent License: T-Cells Transduced with HLA A11 Restricted CT-RCC HERV-E Reactive T-Cell Receptors for the Treatment of Renal Cell Carcinoma

I went to the web page an it was stock wordpress site with almost no information about the group.

https://www.t-curetherapeutic.com/mission/

Can you tell me the names of any of the principals?

Can you explain if any of the persons associated with the firm had worked at the NIH or received any funding from the NIH? Is there any CRADA involved?

Can you explain why this firm, which doesn't seem to be much of anything, should be given a monopoly on HERV-E Reactive T Cell Receptors and Methods of Use patents, for T-cell receptor based cancer immunotherapy for Renal Cell Carcinoma".

Can you tell us if this is considered a start-up license with a low royalty rate?

James Love

--

James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, twitter.com/jamie_love

From: Stevens, Ashley J [astevens@bu.edu]
Sent: 10/25/2016 1:48:20 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
CC: Fred Reinhart (fred@research.umass.edu) [fred@research.umass.edu]
Subject: RE: Publishing the updated drug study

Have you issued a ruling on Xtandi? If so, I missed it.

Best regards,

Ashley

Ashley J. Stevens D.Phil. (Oxon), CLP
President
Focus IP Group, LLC

Office:(781) 721-2670
Cell: b6
astevens@fipgllc.com

From: Rohrbaugh, Mark (NIH/OD) [E] [mailto:RohrBauM@od.nih.gov]
Sent: Tuesday, October 25, 2016 5:15 AM
To: Stevens, Ashley J
Cc: Fred Reinhart (fred@research.umass.edu)
Subject: Re: Publishing the updated drug study

Ashley:

My office is working on a paper on kinase inhibitors starting with Gleevec as a breakthrough. Not focused on source of molecules.

b4

Regards,
Mark

Sent from my iPhone

On Oct 25, 2016, at 9:19 AM, Stevens, Ashley J <astevens@bu.edu> wrote:

b4

b4

Best regards,

Ashley

Ashley J. Stevens, D.Phil(Oxon), CLP, RTTP

<image001.jpg>
President

70 Yale Street, Suite 100
Winchester, MA 01890-2331
Tel: (781) 721-2670
Cell: b6
astevens@fipgllc.com

From: Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]
Sent: 5/16/2018 3:27:37 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: What was NIH response to KEI?????

To Karen's question of whether intramural or extramural KEI decided both. Since the issue began with intramural, I pass to you.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, May 16, 2018 11:22 AM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: Re: What was NIH response to KEI?????

I will check. **b5**

Sent from my iPhone

On May 16, 2018, at 11:11 AM, Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov> wrote:

> This is a KEI question about intramural decisions – **b5**
>
> **From:** Rohrbaugh, Mark (NIH/OD) [E]
> **Sent:** Wednesday, May 16, 2018 10:51 AM
> **To:** Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
> **Subject:** Re: What was NIH response to KEI?????
>
> **b5**
>
> Sent from my iPhone
>
> On May 16, 2018, at 9:46 AM, Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov> wrote:
>
> > Request from KEI to OTT and DEITR, to discuss with KEI the policies and regulations for transfers to subsidiaries and "off-shore" development.
> >
> > **From:** Hammersla, Ann (NIH/OD) [E]
> > **Sent:** Wednesday, May 16, 2018 9:29 AM
> > **To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
> > **Subject:** RE: What was NIH response to KEI?????
> >
> > You were working with Communications about KEI's request to meet on compliance issues
> >
> > **From:** Rohrbaugh, Mark (NIH/OD) [E]
> > **Sent:** Wednesday, May 16, 2018 9:28 AM
> > **To:** Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
> > **Subject:** Re: What was NIH response to KEI?????

On what? I do not recall a recent response

Sent from my iPhone

On May 16, 2018, at 9:24 AM, Hammersla, Ann (NIH/OD) [E]
<hammerslaa@mail.nih.gov> wrote:

> --
> Ann M. Hammersla, J.D.
> Director
> Division of Extramural Inventions and Technology Resources
> Office of Policy for Extramural Research Administration
> Rockledge 1, Suite 310
> 6705 Rockledge Drive
> Bethesda, Maryland 20892-7974
> PHONE: 301-435-0745

From: McGarey, Barbara (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=MCGAREYB]
Sent: 2/20/2017 7:56:48 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Berkley, Dale (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=BERKLEYD]
Subject: Fw: Advice
Attachments: b5

b5

Sent from my BlackBerry 10 smartphone.

From: Tabak, Lawrence (NIH/OD) [E] <Lawrence.Tabak@nih.gov>
Sent: Monday, February 20, 2017 12:52 PM
To: McGarey, Barbara (NIH/OD) [E]
Subject: FW: Advice

Barb,

b5

Thanks

larry

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Monday, February 20, 2017 8:14 AM
To: Tabak, Lawrence (NIH/OD) [E]
Cc: Schwetz, Tara (NIH/OD) [E]
Subject: Advice

Dear Larry,

b5

Thanks

Walter

From: Kurt Fischbeck <fischbeck@ninds.nih.gov>
Date: Sunday, February 19, 2017 at 5:21 PM
To: "Koroshetz, Walter (NIH/NINDS) [E]" <koroshetzw@ninds.nih.gov>, Avi Nath <avindra.nath@nih.gov>
Subject: b5

Dear Walter, Avi:

b5

Thanks!

Kurt

b5

b5

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[redacted]

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[redacted] [redacted]

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[redacted]

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[redacted]

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[redacted]

b5

[redacted]

b5

From: Joe Allen [jallen@allen-assoc.com]
Sent: 1/24/2019 3:49:22 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Hammersla, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87fb28aa23744c0b855ef0683ac2e8b4-hammerslaa]
Subject: Jamie Love's comments on NIST ROI green paper
Attachments: KEI comments on NIST green paper.pdf

We knew this had to be coming and here it is

--

Joseph P. Allen
President
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KEI Comments Regarding the NIST Special Publication 1234 Draft Green Paper on Return on Public Investment

January 9, 2018

Introduction 1

Government Use License (Royalty-Free Right in Inventions) 3

- Intended Action 1. 4
- Consequence of Intended Action 1 5

March-in Rights 6

- Intended Action 2. 6
- Consequence of Intended Action 2 7

Commentary 8

- What is a "Compelling National Issue"? 8
- The Policy and Objective of the Bayh-Dole Act as Described in the Statute 8
- The Bayh-Dole Act Statutory Standards for March-in Rights 9
- Available to the Public on Reasonable Terms 10
- The Culture of Private Benefit from Public Funded Research 11

Increasing Interest in the Use of Royalty-free or March-in Rights in Federally-funded Biomedical Inventions 11

- Table 1: Examples of march-in and royalty-free cases 12
- Two potential march-in or royalty-free rights cases 14
- CRISPR and CAR T 14
- Relationship Between Royalty-free and March-in rights and 35 USC § 1498. 15

The Views of Senators Birch Bayh and Robert Dole 16

  - Bayh's Views Shifted with Client's Interests 17
  - Dole was a Spokesperson for Viagra, Employed by Pfizer and Representing other Corporate Clients 19

Introduction

In December 2018, the Department of Commerce National Institute of Standards (NIST) published NIST Special Publication 1234, "Return on Investment Initiative for Unleashing American Innovation," as a draft Green Paper. According to the initial release (prior to the government shutdown), comments were due by January 9, 2019.

The publication was available from: https://doi.org/10.6028/NIST.SP.1234, but is currently offline due to the federal government shutdown.

The draft Green Paper is 135 pages long, with 313 footnotes, and 8 pages of references. On page 7, there is a "Summary of Intended Actions" which is divided into 5 strategies.

The initiative was launched after the April 19, 2018 "Unleashing American Innovation Symposium" in Washington, DC, and followed four public hearings and a request for comments noticed on May 1, 2018 (83 FR 19052). The initial comment period closed July 30, 2018.

What started out as a review of licensing practices by federal labs has become a broader attack on reasonable pricing obligations for drugs and other inventions, and on several measures designed to enhance the private returns on public investments in research and development (R&D).

While some of the proposals may be promising, others are designed to neuter safeguards written into the Bayh-Dole Act, and in particular, to protect companies that sell expensive drugs, vaccines, diagnostic tests and gene- and cell-treatments like chimeric antigen receptor T-cell (CAR T) therapies from obligations to ensure products are affordable and accessible.

Among the recommendations are proposals to modify statutes to extend copyright of software authored by federal employees,[1] raise the cap on the amount in royalties federal employees can earn to $0.5 million per year,[2] and implement other measures such as the adoption of "business-friendly intellectual property rights"[3] in licensing agreements. The paper also includes a number of proposals by "stakeholders" to modify U.S. patent law on everything from standards for patentability to the USPTO post-grant review of patent claims and the enforcement of injunctions for patent infringement, which would serve to overturn eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388.[4]

Among the appalling recommendations in the draft Green Paper are those that relate to three public interest safeguards in the Bayh-Dole Act, including:

1. The federal government's royalty-free right to inventions it funded, as mandated under 35 USC § 202 and 35 USC § 209;
2. March-in rights on federally-funded inventions, under 35 USC § 203; and
3. The obligation to bring federally-funded inventions to practical application, including in particular the requirement that the benefits of the inventions be made "available to the public on reasonable terms."

---

[1] Pages 38-43.

[2] Pages 49-50.

[3] Page 61, on extending the provisions of the Agreement for Commercializing Technology (ACT).

[4] Page 26, See "What we heard: America Invents Act."

The draft Green Paper includes analysis that is in some cases factually incorrect, incomplete or out of context, and/or lacks balance, in order to justify the argument that the U.S. government should not use its rights in federally-funded inventions to ensure that biomedical products and services are reasonably priced, or to otherwise justify the expansion of private rights in publicly-funded inventions.

Our comments begin by reviewing the proposed changes in the regulations and policies relating to the use of the royalty-free and march-in rights in federally-funded patents, and the efforts to use regulations to narrow the statutory definition of "available to the public on reasonable terms."

Government Use License (Royalty-Free Right in Inventions)

The federal government currently has a royalty-free right to use any invention it funded, worldwide. The statutory obligations for retaining such rights include 35 USC § 202 and 35 USC § 209.

For example, in 35 USC § 202, "Disposition of rights," the Bayh-Dole Act states:

> (4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: *Provided*, That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreement relating to weapons development and production.

There is a similar provision in 35 USC § 209, concerning federally-owned inventions.

Note that the statue ensures the government retains the right "to practice or have practiced for or on behalf of the United States" the federally-funded invention. This right is limited, but only in that the royalty-free right has be used "for or on behalf" of the United States.

The Green Paper *Intended Action 1* proposes policies and regulations to limit such rights.

Intended Action 1.

Define the scope of the "government use license" for use directly by the government—or a government contractor in the performance of an agreement with the government—for a government purpose only, including continued use in research and development by the government. The scope of the government use license should not extend to goods and services made, sold, or otherwise distributed by third parties if the government—or a government contractor in the performance of an agreement with the government—does not directly use or consume those goods and services.

A. UPDATE DEFINITION OF GOVERNMENT USE LICENSE FOR EXTRAMURAL R&D PROGRAMS

Implement regulatory change under the Bayh-Dole Act to (i) update the definition of government use license and its use directly by the government—or a government contractor in the performance of an agreement with the government—for government purpose only and not for the use of a third party,43 and (ii) clarify the appropriate processes and use of the government use right based on a consistent interpretation of the definition restricting its scope of use.44

B. UPDATE DEFINITION OF GOVERNMENT USE LICENSE FOR INTRAMURAL AND PARTNERSHIP R&D PROGRAMS

Implement regulations under the Stevenson-Wydler Act/45/ (consistent with the Bayh-Dole regulatory change) to (i) update the definition of government use license and its use directly by the government for government purpose only and not for use by a third party, and (ii) clarify the appropriate processes and use of the government use right based on a consistent interpretation of the definition restricting its scope of use.

/footnote 42/ U.S. Government Accountability Office (GAO). 2003. "Agencies' Rights to Federally Sponsored Biomedical Inventions." https://www.gao.gov/new.items/d03536.pdf

/footnote 43/ Two regulatory changes suggested:

> * Insert new definition in 37 CFR 401.2: "The term government use is defined as use directly by the government for a government purpose and

> the direct benefit of an agency, not to the benefit of a third party even if related to the government mission. Continued use in research and development by the government is included."
>
> * Insert new language into existing standard patent rights clause in 37 CFR 401.14(b) "Allocation of Principal Rights" clause: "The government use license is restricted by the following conditions:
>
> (A) for use directly by the government or on behalf of the government for its own consumption or practice for its own direct benefit. (B) to continue to perform research. (C) This right does not extend authority to third parties to make, sell, or otherwise distribute goods and services as a commercial product where the government is not procuring the goods or services for its own direct use or consumption through a contract."
>
> /footnote 44/ 37 CFR 401.14
>
> /footnote 45/ Regulatory authority to implement the Stevenson-Wydler Act will require legislative change. The planned action is discussed under Strategy 1, Section G.

Consequence of Intended Action 1

The consequence of *Intended Action 1* would be that the government license would protect uses only when the government uses an invention "for its own consumption or practice for its own direct benefit"(emphasis added) and "to continue to perform research" but would prohibit the use of the license in cases where "the government is not procuring the goods or services for its own direct use or consumption through a contract."

The primary motivation for the proposal in *Intended Action 1* is to **limit** the use of the government's royalty-free right to provide the **public access to affordable versions** of patented drugs, vaccines, gene- and cell-treatments and other therapies and diagnostics that are based upon federally-funded patented inventions.

March-in Rights

There are 63 references to march-in rights in the draft Green Paper.

The proposals to narrow the use of march-in rights are set out in *Intended Action 2*.

Intended Action 2.

Define the circumstances under which the government may exercise march-in rights consistent with the uses of march-in specified in statute and not as a regulatory mechanism for the Federal Government to control the market price of goods and services.

A. DEFINE CIRCUMSTANCES UNDER WHICH MARCH-IN RIGHTS MAY BE EXERCISED

Implement regulatory change under the Bayh-Dole Act to make explicit that the use of march-in rights specified in statute is reserved for a compelling national issue or declared national emergency when other remedies have failed. When a Federal agency receives information that it believes might warrant march-in, regulation will require that the agency first conduct an informal consultation with the contractor, grantee, or licensee to understand the nature of the issue and consider other potential alternatives to remedy the concern. The agency will summarize the efforts made to correct the non-compliance when notifying the contractor or licensee if it intends to proceed with a potential march-in action.

B. CLARIFY AMBIGUITIES IN MARCH-IN RIGHTS PROCESSES AND TERMINOLOGY Implement regulatory change under the Bayh-Dole Act by specifying that march-in rights should not be used as a mechanism to control or regulate the market price of goods and services. Provide a clear and consistent definition for "reasonable terms" contained within the existing statutory definition of "practical application." Clarify the intent of reasonable licensing terms to allow a product or service to reach the marketplace but not as terms (i.e., price control mechanism) for consumer use. 59 , 60 Clarifications for "reasonable terms" and "practical application" should allow flexibility in crafting commercial or other terms in license agreements to achieve effective technology transfer.

/footnote 59/ 37 CFR 401.14(j) details the march-in rights in standard Bayh-Dole Act patent rights. The four enumerated circumstances that the government would elect to assert march-in rights are: 1) contractor has not taken or is not expected to take effective steps to achieve practical application of the subject invention, 2) there is a health or safety need which is not reasonably satisfied by contractor or its licensees, 3) there is a public use requirement specified by Federal regulations that are not reasonably satisfied by contractor or its licensee, and 4) march-in is necessary because of preference of U.S. manufacturing has not been met, a waiver was not granted or obtained, or licensee is in breach of such agreement. Suggested changes to the enumerated circumstances may include language that makes clear that march-in will not be used for anti-competitive reasons such as price control. 37 CFR 401.6 details the procedures that govern the exercise of march-in rights. Language may be added to this section to provide procedural guidance regarding march-in right proceedings, fact finding, and determination.

/footnote 60/ 37 CFR 401.2 is the definitions section for Bayh-Dole Act rights regulation. The current definition of practical application, per 401.2(e), is "The term practical application means to manufacture in the case of a composition of product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being used and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms." The bolded text has been used to support the use of march-in rights as a price control mechanisms as reasonable terms has been interpreted to mean "low price."

Consequence of Intended Action 2

One of the proposed actions in *Intended Action 2* is to limit the circumstances in which a march-in can be used to situations where there is "a compelling national issue or declared national emergency when other remedies have failed." This is a higher standard than set out in the statue, and presents issues that a rights holder can litigate, making it all the more difficult to use march-in rights.

Another proposed action is to issue regulations that greatly narrow the definition of "available to the public on reasonable terms" (emphasis added). Specially, the draft Green paper would require statements:

specifying that march-in rights should not be used as a mechanism to control or regulate the market price of goods and services. Provide a clear and consistent definition for "reasonable terms" contained within the existing statutory definition of "practical application." Clarify the intent of reasonable licensing terms to allow a product or service to reach the marketplace **but not** as terms (i.e., price control mechanism) **for consumer use**. (emphasis added)

Commentary

What is a "Compelling National Issue"?

The draft proposal would limit march-in cases to a "compelling national issue or declared national emergency."

Unless a "declared national emergency" can fail to qualify as a "compelling national issue," the reference to a declared national emergency seems either unnecessary, or designed to color the standard in a way that will narrow the use of march-in rights.

Ultimately, what the Green Paper proposes is to eliminate the use of march-in rights when there are abuses of patent rights, unless such abuses meet some vague standard of being a "compelling national issue." The new standard is vague and invites litigation, for example:

- Are unreasonable prices for biomedical inventions "a compelling national issue"?
- Is a specific overpriced drug or cell therapy for breast cancer a "compelling national issue"?
- Was a shortage of Fabrazyme, which was a personal tragedy for patients, a "compelling national issue"?
- If the NIH threatens to use march-in rights if patent holders don't have more liberal licensing terms for upstream uses of patents on stem cells or CRISPR inventions, does that meet the "compelling national issue" standard?

The Policy and Objective of the Bayh-Dole Act as Described in the Statute

The Bayh-Dole statutes give a much broader mandate for the use of the royalty-free or march-in rights. The "Policy and objective" of the Act is set out in 35 U.S. Code § 200, and includes this mandate:

> It is the policy and objective of the Congress . . to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; (emphasis added)

The Bayh-Dole Act Statutory Standards for March-in Rights

The specific grounds for using the march-in rights do not require extreme tests, or meeting the proposed and vague status of "compelling national issue." On the contrary, they are fairly straight forward:

> (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
>
> (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
>
> (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
>
> (4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

The problem today is not that agencies use the march-in rights too frequently, but rather on the contrary, that the rights are rarely invoked, despite cases where there is a clear abuse of patent rights.

In January 2016, 51 members of Congress wrote to HHS Secretary Sylvia Mathews Burwell and NIH Director Francis S. Collins (copy at https://www.keionline.org/22983) urging both "to utilize your existing statutory authority to respond to the soaring cost of pharmaceuticals," noting:

> When declining to exercise these march-in rights in response to previous petitions, NIH has suggested that controlling drug costs is a legislative duty. While that is accurate, Congress legislated long ago on a bipartisan basis in delegating authority to federal agencies such as NIH the responsibility to address one aspect of this problem. We call upon you to do that job. The failure to act in the past has undoubtedly sent an unfortunate signal that prices for federally-funded inventions can be set as high as a sick

> or dying consumer will pay. In 2013, for example, NIH rejected a request to issue rules related to pricing disparities between the United States and other high-income countries. While this may not be the sole standard considered, it exemplifies the type of standard which could be set.

In the Senate report to accompany the National Defense Authorization Act for Fiscal Year 2018, the Senate Committee on Armed Services sought to remedy this for a different funding agency by providing a directive to the Department of Defense:[5]

> **Licensing of federally owned medical inventions**
> The committee directs the Department of Defense (DOD) to exercise its rights under sections 209(d)(1) or 203 of title 35, United States Code, to authorize third parties to use inventions that benefited from DOD funding whenever the price of a drug, vaccine, or other medical technology is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States.

Both the 2016 Congressional letter and the 2017 National Defense Authorization directive focused on a particular rule that could be invoked to protect U.S. residents from unreasonable prices, namely that U.S. residents should not pay more than residents of other high income countries for drugs where public funds were used for the patented inventions. The 2016 Congressional letter and the 2017 directive to the DoD were motivated by public debate on the problem of high drug prices, which is certainly a “compelling national issue.”

Available to the Public on Reasonable Terms

The draft Green Paper seeks to narrow the meaning of the statutory requirement to make the benefits of inventions “available to the public on reasonable terms.” This obligation is found in the statutory definition of “practical application”, in 35 USC § 201(f) of the Bayh-Dole Act, which reads as follows:

> (f) The term “practical application” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms. (emphasis added)

Dr. Francis Collins and before him Elias A. Zerhouni, M.D both have taken the position that obligation to make the benefits of inventions “available to the public on reasonable terms” will be satisfied if a company makes a product “available to the public at any price.” This is a tortured interpretation of “available to the public on reasonable terms”. Price is the term that counts the most for “the public.” What other terms do NIST experts think the public is concerned about?

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[5] 115TH Congress, 1st Session, 2017, Senate Report 115-125. National Defense Authorization Act for Fiscal Year 2018. Report to accompany S. 1519, on page 173

The Culture of Private Benefit from Public Funded Research

The culture at the NIH is to ignore concerns the public has over the pricing of products. NIH scientists themselves are often named as inventors on patents, and under current law, are able to receive as much as $150,000 per year in royalties on such inventions, while employed by the NIH, in addition to whatever salary they earn. The Green Paper is proposing increasing the royalty cap to $0.5 million per year for all federal employees.

In 2016, KEI requested from the NIH records on royalty payments to its employees. The NIH has yet to provide such information.

Federal employees also often leave the government and join biomedical companies, large and small. There is an extensive revolving door, from the government and government-funded research institutions to private industry, and sometimes back to government or non-profit research jobs.

For example, until April 2018, Dr. Zerhouni was the President for Global Research and Development at the French pharmaceutical company Sanofi. Charles Sawyers, MD, from Sloan Kettering, is the principal investigator for more than $26 million in NIH grants from 1990 to 2018, including $5 million for 2017-2018 fiscal years. He has also advised the U.S. Army on prostate cancer research, co-founded biotechnology companies, and holds a seat on the Novartis Board of Directors, while working with Vice President Biden and NIH Director Francis Collins on the Cancer Moonshot. It is not surprising that many NIH-funded researchers support policies on government-funded research that provide huge benefits to private interests.

Increasing Interest in the Use of Royalty-free or March-in Rights in Federally-funded Biomedical Inventions

In general, federal agencies have been reluctant to use the government’s royalty-free rights or the funding agency’s march-in rights in federally-funded inventions. That said, such rights have been used in the past, and there is increasing interest in such use going forward.

Table 1 provides a list of notable cases where various federal agencies have considered or been asked to consider the use of royalty-free or march-in rights to address issues of drug pricing and affordability, shortages of products, or use of technologies to create new biomedical products, involving the NIH, the CDC, DOE and the U.S. Army.

Table 1: Examples of march-in and royalty-free cases

Type	**Year**	**Invention/product**	**Petitioner or intended petitioner, and outcome**
March-in	1997	Ceprate SC, bone marrow transplantation	CellPro v Johns Hopkins, Link Outcome: CellPro was able to stay an injunction until a competing product was FDA approved, benefiting CellPro and patients using the CellPro device, but CellPro ultimately failed to obtain a license. Of note: Former Senator Birch Bayh represented Cellpro, and argued that John Hopkins University's demand for high royalties would lead to high prices and that high prices would have a negative impact on patients.
March-in	1999	Fluorescent in situ hybridization tests	Ventana Medical Systems (now owned by Roche) *v* the University of California. Outcome: DOE had funded the technology. After a 30-month fact-finding process determination by DOE, Ventana was able to obtain a license and marketed a FISH test in competition with Vysis, a subsidiary of Abbott laboratories.
Royalty-free	1999	Several drugs	Ralph Nader, CPTech and Essential Action, Link Outcome: NIH Director Dr. Harold Varmus rejected the request to allow the World Health Organization (WHO) to use the U.S. government's royalty-free rights in drug patents in low income countries.
March-in/royalty-fr	2001	Stem cells	WARF

ee (threat)			Outcome: NIH negotiated two agreements with WARF on licensing stem cell patents.
March-in	2004	Norvir/ritonavir	Essential Inventions v Abbott, Link Outcome: NIH rejected the march-in request, but only after Abbott agreed to roll back a 400 percent price hike for patients on federal programs.
March-in	2004	Latanoprost	Essential Inventions v Pfizer, Link Outcome: NIH rejected the march-in request.
March-in (threat)	2006	Reverse genetics for avian flu	Centers for Disease Control Outcome: More liberal licensing of reverse genetics patents.
Royalty-free	2007	Stavudine/d4T and ritonavir	Essential Inventions, Link Outcome: OMB head Robert Porter rejected the request to use the federal royalty-free rights.
March-in	2010	Fabrazyme shortage	Joseph M. Carik, Anita Hochendoner, and Anita Bova v Mount Sinai School of Medicine of New York University/Sanofi/Genzyme, Link Outcome: The NIH prevented Genzyme/Sanofi from enforcing an injunction against Shire in Germany until Sanofi restored manufacturing capacity.
March-in, royalty-free	2012	Ritonavir and other drugs	American Medical Students Association (AMSA), Knowledge Ecology International (KEI), U.S. Public Interest Research Group (PIRG) and the Universities Allied for Essential Medicines (UAEM), Link Outcome: NIH rejected march-in request.

March-in, royalty-free	2016	Xtandi (enzalutamide)	Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT) v University of California/Astellas, Link Outcome: NIH rejected march-in request andU.S. Army rejected march-in request.
March-in, royalty-free	2017	Zinbryta (daclizumab)	Knowledge Ecology International (KEI), Link Outcome: Product withdrawn from market.
March-in/royalty free right (ongoing campaign)	2018	Truvada (emtricitabine/tenofovir disoproxil fumarate)	PrEP4All v Gilead Outcome: Ongoing. HHS has not yet acted.

Two potential march-in or royalty-free rights cases

The following are two cases where the use of royalty-free or march-in rights are under active consideration, and which would be prejudiced by the proposed changes in *Intended Actions 1* and *2*.

1. Spinraza/nusinersen. The high price of Spinraza ($750,000 for first year of treatment, and $375,000 for maintenance) has created restrictions on access to this treatment for spinal muscular atrophy (SMA) a neuromuscular disorder that harms children. The price for this treatment, invented at the University of Massachusetts and Cold Spring Harbor on NIH grants is reportedly less than $100,000 per year in some European countries.
2. Xtandi/enzalutamide. A veteran is expected to petition the Department of Defense to use its Bayh-Dole rights to enable competition for enzalutamide, a drug for prostate cancer invented on a grant from the U.S. Army that has an average wholesale price of $159,000 per year in the United States, and a much lower price in other high income countries. This petition will ask DoD to apply the 2017 DoD authorization directive described above.

CRISPR and CAR T

Extensive patent thickets are emerging in CRISPR and CAR T technologies, two promising areas of biomedical innovation.

On June 6, 2017, Knowledge Ecology International wrote to the U.S. Department of Health and Human Services (DHHS) asking the Department to adopt a policy on the licensing of federally-funded CRISPR patented inventions (link here). The NIH has declined to do so, but at a future date, under different leadership, may revisit this issue.

CAR T-Cell therapies are also plagued with extensive patent filings and overlapping claims, leading to considerable litigation, high costs for acquiring intellectual property rights and legal-related business risks.

For both CRISPR and CAR T, the NIH has played a key role in funding the most important and foundational innovations, and can use the royalty-free and march-in rights to pressure rights holders to more liberally license platform patents.

Relationship Between Royalty-free and March-in rights and 35 USC § 1498.

35 USC §1498(a) "Patent and copyright cases," provides for a limitation on the remedies for nonvoluntary government use of patented inventions. Injunctions are not available, but patent holders are entitled to compensation, which is set by courts. Proposals have been made since 2001 to use §1498(a) to obtain low cost generic versions of a variety of drugs, including in 2001 CIPRO/ciprofloxacin, in 2005-6 Tamiflu/oseltamivir, in 2006 Avastin/Bevacizumab, in 2014-2018 sofosbuvir-based HCV drugs, and in 2016-2018, various anti-overdose remedies. (See: https://www.keionline.org/cl/28usc1498). A constant objection from federal agencies is the risk of a costly compensation obligation, by a federal court.

In the ritonavir march-in cases, the NIH expressed concern that a march-in license on the federally-funded inventions would not be sufficient, if other non-federally-funded patents were infringed.

The Section 202 and 209 government use license can mitigate the risks of large judgements for non-voluntary use of patents, and Section 1498 can mitigate the problem of not having access to all relevant patents under march-in. Taken together, Section 1498 can clear out any evergreening patents that may present issues, and the Section 202 or 209 licenses can eliminate the risk of large compensation judgements. The draft Green paper would limit the ability of the federal government to take advantage of these opportunities where there is a clear need to remedy an excessive price.

The 202 and 209 licenses can also be used to register drugs, as noted by Alfred Engelberg and Aaron Kesselheim in a 2016 article in Nature Medicine.[6]

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[6] "Use the Bayh-Dole Act to lower drug prices for government healthcare programs," Nature Medicine 22, 576 (2016) doi:10.1038/nm0616-576, Published online 07 June 2016.

Hatch-Waxman requires a manufacturer that is seeking approval to sell a generic copy of a patented new drug like enzalutamide to certify that any patents on the new drug are invalid or will not be infringed. This requirement may seem to prevent a generic manufacturer that has no basis for substantively challenging enzalutamide's patents from obtaining FDA approval before the patents expire. But because of the government's Section 202 license, we believe that a generic manufacturer could certify that the patents will not be infringed because approval is being sought for the sole purpose producing enzalutamide for sale to the government. Any suit claiming infringement of the enzalutamide patents despite such a certification should be dismissed by a federal court, because law /fn3/ prohibits the court from interfering with the right of a government supplier to bid on or participate in the sale of products to the government, irrespective of the existence of patents. /fn4/ The only available course of action for acts of patent infringement by or for the government is to initiate a suit in the US Court of Federal Claims—but the Section 202 license would provide the government with a complete defense.
fn3/ 28 USC 1498(a)
fn4/ Gore v. Garlock, 842 F.2d 1275, 1282 (Fed. Cir. 1988).

The Views of Senators Birch Bayh and Robert Dole

The draft Green Paper quotes former U.S. Senators Bayh and Dole to support the notion that march-in was not intended to address pricing issues.

This deserves some commentary. First, this is how the Green Paper presented the views of Senators Bayh and Dole:

> The original sponsors of the Bayh-Dole Act have noted that their intent was to ensure that products were licensed for reasonable terms rather than being used as a price control. (Refer to "Statements by Senators Bayh and Dole on March-In.")
>
> **Statements by Senators Bayh and Dole on March-In**
> The "Bayh-Dole [Act] did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that

---

http://www.nature.com/nm/journal/v22/n6/abs/nm0616-576.html should be dictated by the government...The ability of the government to revoke a license granted under the [Act] is not contingent on the pricing of the resulting product or tied to the profitability of a company that has commercialized a product that results in part from [federally] funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product," among other circumstances.

Source: Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," Washington Post, April 11, 2002.

The Green Paper quotes a letter to the editor by Bayh and Dole[7], responding to an op-ed and earlier academic article by Professors Peter Arno and Michael Davis.[8]

Bayh's Views Shifted with Client's Interests

Bayh would later repeat this argument in the 2004 hearing on ritonavir march-in petition, in support of Abbott. At the 2004 hearing, Bayh claimed that no one had paid him to testify at the hearing. What he neglected to disclose, was that he was a partner in a firm representing Abbott. Moreover, Bayh neglected to note that in 1997, he represented Cellpro in a march-in request, and made the contrary argument.

In enacting Bayh-Dole, Congress made the judgment that policy objectives of commercializing the results of federally-funded research were better served by allowing federal nonprofit grantee institutions like Johns Hopkins to obtain and hold patent rights, with exploitation of inventions generally left to the nonprofits' licensing programs and competitive forces. At the same time, however, Congress recognized that in particular cases the public interest might require government action and therefore included in the Act 'march-in' provisions "to ensure that the

---

[7] Letter to the editor, Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," *Washington Post*, April 11, 2002, page A28.

[8] Peter Arno & Michael Davis, Paying Twice For the Same Drugs, *Washington Post*, March 27, 2002, page A21; summarizing their earlier academic article, Peter Arno & Michael Davis, (2001) Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research, 75 TULANE L. REV. 631.

> Government obtains sufficient rights in federally supported inventions to . . . protect the public against nonuse or unreasonable use of inventions." . . .
>
> To carry out these federal policies, the Bayh-Dole Act provides that a Federal agency may exercise its march-in rights and require the exclusive licensee of an invention made with Federal funds to issue a license to a responsible applicant's "upon terms that are reasonable under the circumstances" if the Federal agency determines that
>
> > (a) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use; [or]
> >
> > (b) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees. 35 U.S.C. 203.
>
> In the present instance, both of these statutory bases have plainly been met.
>
> . . .
>
> In fact, the circumstances — and the interests of the public which paid for the research that led to the patents and is now being asked to pay again — cry out for a far lower royalty payment by CellPro.
>
> . . .
>
> CellPro submits that there may well be reason for the government to adopt regulations covering situations like the present where the same product may be claimed to be covered by patents arising out of work done by more than one federal grantee. Moreover, investigation may be needed to determine whether the royalty layering that plainly exists in the present case . . . is a common problem that leads to unreasonably high royalties (and prices of medical care) that should be dealt with by regulation.
>
> Source: The March 3, 1997 march-in petition to Secretary Donna E. Shalala from Lloyd Cutler and Birch Bayh, on behalf of Cellpro. (Copy here).

Bayh's views, set out in an amicus brief, on what the Bayh-Dole Act required regarding the ownership of federally funded inventions, was rejected by the U.S. Supreme Court in Stanford University v. Roche Molecular Systems, Inc., 563 U.S. 776 (2011), illustrating the risks of relying upon the recollections and opinions of former members of Congress, as regards the intent of a U.S. statute.

Dole was a Spokesperson for Viagra, Employed by Pfizer and Representing other Corporate Clients

Upon leaving the U.S. Senate, Dole joined Verner, Liipfert, Bernhard, McPherson and Hand, as a lobbyist. In 2003, after Verner, Liipfert was acquired by Piper Rudnick, Dole joined the Washington, D.C. law and lobbying firm Alston & Bird LLP.

By the time Dole co-signed the letter with Bayh, he was working for Pfizer. Dole began doing television commercials for Pfizer in 1998.[9]

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[9] Pfizer Hires Bob Dole for TV Ad Campaign, December 12, 1998, Associated Press. http://articles.latimes.com/1998/dec/12/business/fi-53139

From: Wolinetz, Carrie (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=WOLINETZCDC9A]
Sent: 2/22/2017 1:15:38 AM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: Advice

Thanks for the update!

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, February 21, 2017 4:33 PM
To: Wolinetz, Carrie (NIH/OD) [E]
Subject: Fwd: Advice

Sent from my iPhone

Begin forwarded message:

> **From:** "McGarey, Barbara (NIH/OD) [E]" <MCGAREYB@od.nih.gov>
> **Date:** February 21, 2017 at 4:32:27 PM EST
> **To:** "Tabak, Lawrence (NIH/OD) [E]" <Lawrence.Tabak@nih.gov>
> **Cc:** "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>, "Berkley, Dale (NIH/OD) [E]" <BerkleyD@OD.NIH.GOV>
> **Subject: RE: Advice**
>
> Hi Larry,
>
> I reached out to Mark Rohrbaugh and Dale Berkley, and below is our combined advice:
>
> **b5**
>
> Hope this is helpful, and happy to discuss.
>
> Barbara

Barbara M. McGarey, JD
Deputy Associate General Counsel
Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Rm 2B-50
Bethesda, MD 20892-2111
(301) 496-6043 (p)
(301) 402-1034 (f)
mcgareyb@od.nih.gov

From: Tabak, Lawrence (NIH/OD) [E]
Sent: Monday, February 20, 2017 12:52 PM
To: McGarey, Barbara (NIH/OD) [E] <MCGAREYB@od.nih.gov>
Subject: FW: Advice

Barb,

b5

Thanks
larry

From: Koroshetz, Walter (NIH/NINDS) [E]
Sent: Monday, February 20, 2017 8:14 AM
To: Tabak, Lawrence (NIH/OD) [E]
Cc: Schwetz, Tara (NIH/OD) [E]
Subject: Advice

Dear Larry,

b5

Thanks

Walter

From: Kurt Fischbeck <fischbeck@ninds.nih.gov>
Date: Sunday, February 19, 2017 at 5:21 PM
To: "Koroshetz, Walter (NIH/NINDS) [E]" <koroshetzw@ninds.nih.gov>, Avi Nath <avindra.nath@nih.gov>
Subject: Nusinersen pricing

Dear Walter, Avi:

b5

Thanks!

Kurt

b5

From: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=HAMMERSLAA]
Sent: 6/19/2017 1:44:22 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: Draft CRISPR response

Hello Mark: I have seen the changes - ok and understand the letter has been sent and signed. If you need me this week - you can send an email to b6 and then I will get back on my computer.

Ann

-----Original Message-----
From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Saturday, June 17, 2017 4:26 PM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Cc: Jorgenson, Lyric (NIH/OD) [E] <jorgensonla@od.nih.gov>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>
Subject: Re: Draft CRISPR response

b5

Sent from my iPhone

> On Jun 17, 2017, at 4:24 PM, Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV> wrote:
>
> Ann:
>
> Dale provided edits to our draft and then I made a few small changes from Dale's edited version. All here in track changes. Please review as soon as you are able.
>
> Regards,
> Mark
>
> Sent from my iPhone
> <WF365656 KEI Response OEROSP (002)--OGCBerkleyComments_MR2.docx>

From: Billet, Courtney (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7605EEB349AC41138B32FE3978E3986D-BILLETC]
Sent: 9/12/2017 5:15:28 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]
CC: Eisinger, Robert (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bad2a8c45514ee48985880de66674ad-eisinger]; Stover, Kathy (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c82722674ba14c2f969bd50dfa6a7af4-stoverk]; Haskins, Melinda (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545e01141619453bb4fc1dcde6c45887-haskinsm]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Paules, Catharine (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e3435aa00e54d419df3e535016c19fa-paulesci]
Subject: FINAL -- talking points
Attachments: Talking Points - Licensing -- FINAL.docx

This is the final version of the talking points that I sent forward, reconciling all edits. In the interest of time, b5

b5

Thanks to all for the review and all the helpful (and fast!) comments.

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, September 12, 2017 11:42 AM
To: Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Paules, Catharine (NIH/NIAID) [E] <catharine.paules@nih.gov>
Subject: RE: Zika vax -- talking pts and website language

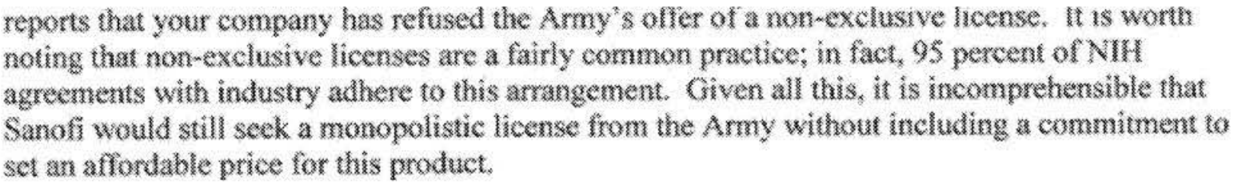
b5

b5

From: Marston, Hilary (NIH/NIAID) [E]
Sent: Tuesday, September 12, 2017 11:12 AM
To: Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Paules, Catharine (NIH/NIAID) [E] <catharine.paules@nih.gov>
Subject: RE: Zika vax -- talking pts and website language

b5

b5 KEI and others have used this "most non-exclusive" point to argue against exclusive licenses (see excerpt below from https://www.keionline.org/sites/default/files/Senate-Letter-to-Sanofi-re-Zika-Vaccine-Army-Pricing.pdf). Is the 95% correct? And what does that 95% actually represent (e.g., licenses to techniques, reagents, etc.). Again – not needed for today, but possibly important for interviews.



reports that your company has refused the Army's offer of a non-exclusive license. It is worth noting that non-exclusive licenses are a fairly common practice; in fact, 95 percent of NIH agreements with industry adhere to this arrangement. Given all this, it is incomprehensible that Sanofi would still seek a monopolistic license from the Army without including a commitment to set an affordable price for this product.

From: Mascola, John (NIH/VRC) [E]
Sent: Tuesday, September 12, 2017 10:57 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: Zika vax -- talking pts and website language

Want to highlight Mark's comment on following text:

b5

Mark's comment: b5

b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, September 12, 2017 10:37 AM
To: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>; Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: Zika vax -- talking pts and website language

I have a few comments on the Talking Points. THx

From: Mowatt, Michael (NIH/NIAID) [E]
Sent: Tuesday, September 12, 2017 10:07 AM
To: Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>; Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>
Subject: RE: Zika vax -- talking pts and website language

Proposed changes tracked and highlighted in yellow.

b5 See my comment.

b5

From: Billet, Courtney (NIH/NIAID) [E]
Sent: Tuesday, September 12, 2017 9:54 AM
To: Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: Zika vax -- talking pts and website language

Ok, thanks

From: Mascola, John (NIH/VRC) [E]
Sent: Tuesday, September 12, 2017 9:53 AM
To: Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: Zika vax -- talking pts and website language

b5

From: Billet, Courtney (NIH/NIAID) [E]
Sent: Tuesday, September 12, 2017 9:13 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: FW: Zika vax -- talking pts and website language

HI all -- Edits from HHS on both documents. Would appreciate your review and response. Hope to send ASF a final for one last review by noon. Thanks

b5

b5

b5

b5

From: Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]
Sent: 8/2/2018 6:33:00 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Vizamyl
Attachments: KEI-Briefing-Note-2018-1.pdf; Azar-KEI-CoverLetter-Vizamyl-patents-18May2018.pdf; Vizamyl-patent-memo-UofPittsburgh-Klunk-Mathis-Wang-18May2018.pdf

---

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, August 02, 2018 2:16 PM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: RE: Vizamyl

Can you send me a copy of the request please?

From: Hammersla, Ann (NIH/OD) [E]
Sent: Thursday, August 02, 2018 1:26 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: FW: Vizamyl

Collins and I were copied on the KEI request.

From: Hammersla, Ann (NIH/OD) [E]
Sent: Thursday, August 02, 2018 1:25 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: Vizamyl

Mark: On 5/18/2018 KEI sent to Secretary Azar a request to march-in on Vizamyl. Have you seen any delegation of this request from the Secretary? I haven't. Do you recommend holding until the Secretary responds? Ann

--
Ann M. Hammersla, J.D.
Director
Division of Extramural Inventions and Technology Resources
Office of Policy for Extramural Research Administration
Rockledge 1, Suite 310
6705 Rockledge Drive
Bethesda, Maryland 20892-7974
PHONE: 301-435-0745

Vizamyl (INN Flutemetamol F 18)

Failures to disclose NIH funding for four patents in the FDA Orange Book invented by William Klunk, Chester Mathis, Jr., and Yanming Wang, and assigned to the University of Pittsburgh

Knowledge Ecology International
May 18, 2018

Table of Contents

Introduction 2

What Does Vizamyl Do? 3

The Orange Book Patents for Vizamyl 4

Table 1: The Orange Book Patents for Vizamyl 4

The Klunk, Mathis, and Wang Patents that Failed to Disclose Federal Funding 4

Table 2: The Four Amyloid Klunk, Mathis and Wang Patents 4

Table 3: NIH-Funded Projects to the University of Pittsburgh from Fiscal Years 1988 to 1999 Listing William Klunk as PI 6

Table 4: NIH-Funded Projects to the University of Pittsburgh from Fiscal Years 2001 to 2002 Listing William Klunk as PI 7

Table 5: The Eight R01 AG018402 Projects Listing Chester Mathis as the PI and the University of Pittsburgh as the Institution 10

Table 6: The Ten P50 AG005133 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution 11

Table 7: The Five K02 AG001039 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution 12

Table 8: The Five R01 AG020226 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution 12

Table 9: The Eleven R37 AG025516 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution 13

Table 10: The Nineteen P01 AG025204 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution 14

Additional Notes on Research Grants from the National Institutes of Health 16

NIH Grants to William Klunk Cited in a 2003 Paper 16

NIH Grants to Chester Mathis Cited in a 2004 Paper 16

NIH Grants to Yanming Wang 17

Table 11: Five NIH Grants to Yanming Wang from 2003-2007 Mentioning Amyloid-based Screening for Alzheimer's and Dementia 19

Why the Wang Grants are Related to the Inventions 19

The Vizamyl Prices 20

Requested Remedies for Non-disclosure 20

ANNEX 1: Select News Reports and Other Background on Vizamyl 21

ANNEX 2: NIH Grants to the University of Pittsburgh with William E. Klunk Listed as Principal Investigator, with Search Term "Amyloid" 21

ANNEX 3: Eighteen Patents Assigned to the University of Pittsburgh that List William E. Klunk as the Inventor 24

ANNEX 4: NIH Grants to the University of Pittsburgh with Chester A. Mathis Listed as Principal Investigator, with Search Term "Amyloid" 25

Introduction

Knowledge Ecology International (KEI) asks the National Institutes of Health (NIH) to investigate whether there has been a failure to disclose NIH research funding on four patents granted that list William E. Klunk, Chester A. Mathis, Jr., and Yanming Wang as inventors. All four patents are assigned to the University of Pittsburgh.

The patents are listed as the first four patents (out of five patents) in the FDA Orange Book for the drug Vizamyl (INN flutemetamol, marketed by GE Healthcare), a nuclear imaging agent for the visualization of β-amyloid neuritic plaque density in patients being evaluated for cognitive disorders such as Alzheimer's disease.

Each of the three inventors received numerous research grants and contracts from the NIH and other federal agencies.

According to the NIH RePORTER database, from 1988 to 2018, William Klunk was the principal investigator for grants obtained from the National Institute of Health, consisting of 52 projects, 35 sub-projects and a total funding amount of $47,209,483.

From 1986 to 2018, Chester A. Mathis, Jr. received NIH grants consisting of 31 projects and 12 subprojects with a total funding amount of $14,936,292.

From 2003 to 2013, Yanming Wang was listed as the principal investigator for 19 NIH projects involving $4,116,038 of funding.

Many of the NIH grants are directly related to the four patented inventions. In addition to the grants disclosed in the NIH RePORTER database, the inventors have disclosed additional research contracts or grants related to the invention from the NIH and the U.S. Department of Energy, in various academic papers describing the inventions.

The inventions are important. William Klunk and Chester Mathis received a $100,000 Potamkin Prize award in 2008 for their research on Alzheimer's disease. Specifically, the prize was awarded for the invention and development of Pittsburgh Compound B (PiB), a radioactive amyloid plaque imaging compound that enables visualization of the β-amyloid plaque deposits (which disrupt the function of brain cells) and distinguishes between the diagnosis of Alzheimer's disease and other types of dementia.[1]

Vizamyl is available in 10 or 30 mL multi-dose glass vials at a strength of 150 MBq/mL (4.05 mCi/mL), the price of 1 vial (5 mCi) is approximately $28,000. Medicare restricts reimbursements for the tests.[2]

KEI is asking the NIH to take title to the patents, which is an available remedy under the Bayh-Dole Act for non-disclosure of federal funding of patented inventions. At a minimum, the Department of Health and Human Services should require the University of Pittsburgh to correct the failure to disclose the NIH grants.

What Does Vizamyl Do?

GE Healthcare[3] provides the following information on Vizamyl:

> Vizamyl is an imaging drug (also called a tracer) that is injected into a person's bloodstream before a positron-emission tomography (PET) scan is performed. Currently, Vizamyl is the first-and-only imaging drug approved to provide color PET images that help your doctor estimate the amount of a protein called beta amyloid in the brain.
>
> Although most people will develop some beta amyloid in the brain during aging, those with Alzheimer's disease tend to develop more than those who do not have the disease.
>
> ...A short time after Vizamyl is injected into the bloodstream, it will attach to beta amyloid in the brain. An imaging device called a PET scanner will then take color images of the brain. A radiologist can use these images to estimate how much beta amyloid there is.

---

[1] Klunk and Mathis Win Prestigious Potamkin Prize For Alzheimer's Research. 2008

[2] Final Decision Memorandum for: CAG-00431N Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease, September 27, 2013. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=265

[3] About Vizamyl. 2017

In 2010, the Centers for Disease Control reported an estimate of 5.4 million Americans affected by Alzheimer's, ranking the illness the "sixth leading cause of death among all adults and the fifth leading cause of death for those aged 65 or older".[4]

The Orange Book Patents for Vizamyl

The May 10, 2018 version of the FDA Orange Book lists five patents for Vizamyl. Four patents were assigned to the University of Pittsburgh and one was assigned to GE Healthcare Limited, in Buckinghamshire, Great Britain.

Table 1: The Orange Book Patents for Vizamyl

Patent Number	Grant	Expiration	Inventors	Assignee
7270800	9/18/2007	09/03/2025	Klunk; William E. (Pittsburgh, PA), Mathis, Jr.; Chester A. (Pittsburgh, PA), Wang; Yanming (Imperial, PA)	University of Pittsburgh
7351401	4/1/2008	01/24/2023	Klunk; William E. (Pittsburgh, PA), Mathis, Jr.; Chester A. (Pittsburgh, PA), Wang; Yanming (Imperial, PA)	University of Pittsburgh
8236282	8/8/2012	05/21/2024	Klunk; William E. (Pittsburgh, PA), Mathis, Jr.; Chester A. (Pittsburgh, PA), Wang; Yanming (Imperial, PA)	University of Pittsburgh
8691185	4/8/2014	01/24/2023	Klunk; William E. (Pittsburgh, PA), Mathis, Jr.; Chester A. (Pittsburgh, PA), Wang; Yanming (Imperial, PA)	University of Pittsburgh
8916131	12/23/2014	09/16/2028	Roed; Line (Oslo, NO), Peterson; Sarah Elizabeth (Amersham, GB)	GE Healthcare Limited (Buckinghamshire, GB)

The Klunk, Mathis, and Wang Patents that Failed to Disclose Federal Funding

The four University of Pittsburgh patents failed to disclose federal funding in the invention. The priority, file and grant dates, title, and abstract for the patents are listed in Table 2.

Table 2: The Four Amyloid Klunk, Mathis and Wang Patents

Patent Number	Priority Date	File Date	Grant Date	Title	Abstract
7270800	8/24/2000	3/14/2003	9/18/2007	Thioflavin derivatives for use in antemortem diagnosis of	This invention relates to novel thioflavin derivatives, methods of using the derivatives in, for example, in vivo imaging of patients having neuritic plaques, pharmaceutical compositions comprising the thioflavin

---

[4] Promoting Health and Independence for an Aging Population At A Glance 2017, September 12, 2017

				Alzheimer's disease and in vivo imaging and prevention of amyloid deposition	derivatives and method of synthesizing the compounds. The compounds find particular use in the diagnosis and treatment of patients having diseases where accumulation of neuritic plaques are prevalent. The disease states or maladies include but are not limited to Alzheimer's disease, familial Alzheimer's disease, Down's Syndrome and homozygotes for the apolipoprotein E4 allele.
7351401	8/24/2000	6/3/2004	4/01/2008	Thioflavin derivatives for use in the antemortem diagnosis of Alzheimers disease and in vivo imaging and prevention of amyloid deposition	This invention relates to novel thioflavin derivatives, methods of using the derivatives in, for example, in vivo imaging of patients having neuritic plaques, pharmaceutical compositions comprising the thioflavin derivatives and method of synthesizing the compounds. The compounds find particular use in the diagnosis and treatment of patients having diseases where accumulation of neuritic plaques are prevalent. The disease states or maladies include but are not limited to Alzheimer's Disease, familial Alzheimer's Disease, Down's Syndrome and homozygotes for the apolipoprotein E4 allele.
8236282	8/22/2003	9/30/2009	8/7/2012	Benzothiazole derivative compounds, compositions and uses	This invention provides benzothiazole derivative compounds, compositions comprising such compounds, methods of preparing such compounds, and methods of using such compounds for detecting amyloid deposit(s) and for diagnosing a disease, disorder or condition characterized by amyloid deposit(s).
8691185	08/22/2003	7/12/2012	4/8/2014	Benzothiazole derivative compounds, compositions and uses	This invention provides benzothiazole derivative compounds, compositions comprising such compounds, methods of preparing such compounds, and methods of using such compounds for detecting amyloid deposit(s) and for diagnosing a disease, disorder or condition characterized by amyloid deposit(s).

Note that all four patents have the same three inventors (Klunk, Mathis and Wang). The first two patents have the same title, abstract and priority date. The last two patents have the same title, abstract and priority date.

The 7,270,800 and 7,351,401 patents

The 7,270,800 and 7,351,401 patents have the same three inventors (Klunk, Mathis and Wang), title and abstract, with somewhat different claims. The inventions involve novel thioflavin derivatives, and their use in in vivo imaging, for diagnosis and treatment of patients having diseases where accumulation of neuritic plaques are prevalent, including but not limited to Alzheimer's disease. The priority date for both patents is August 24, 2000, and the filing dates were May 14, 2003 and June 3, 2004.

Table 3 lists eight NIH-funded projects by the University of Pittsburgh from 1988 to 1999 that list William Klunk as the Principal Investigator. This is the time leading up to the priority date for patents 7,270,800 and 7,351,401.

Table 3: NIH-Funded Projects to the University of Pittsburgh from Fiscal Years 1988 to 1999 Listing William Klunk as PI

Project Number	Title	FY	Agency	Amount
1 F32 AG005443 01	MOLECULAR PROBES FOR ALZHEIMER BETA-AMYLOID PROTEIN	1988	NIA	$27,000
5 F32 AG005443 02	MOLECULAR PROBES FOR ALZHEIMER BETA-AMYLOID PROTEIN	1989	NIA	$31,750
5 R01 AG005657 06	NMR STUDIES OF BRAIN AGING IN ALZHEIMER'S DISEASE	1990	NIA	$139,105
1 R29 MH053310 01A1	CLINICAL METABOLIC CORRELATION IN DEMENTIA BY PROTON NMR	1995	NIMH	$98,405
5 R29 MH053310 02	CLINICAL METABOLIC CORRELATION IN DEMENTIA BY PROTON NMR	1996	NIMH	$101,910
5 R29 MH053310 03	CLINICAL METABOLIC CORRELATION IN DEMENTIA BY PROTON NMR	1997	NIMH	$105,204
5 R29 MH053310 04	CLINICAL METABOLIC CORRELATION IN DEMENTIA BY PROTON NMR	1998	NIMH	$108,621
5 R29 MH053310 05	CLINICAL METABOLIC CORRELATION IN DEMENTIA BY PROTON NMR	1999	NIMH	$112,536

The budget end date for project 5R29MH053310-05 was June 30, 2000, less than two months before the priority date of the two patents. The abstract for that grant reads as follows:

Project Number: 5R29MH053310-05
Contact PI / Project Leader: Klunk, William E
Title: Clinical Metabolic Correlation In Dementia By Proton NMR
Awardee Organization: University Of Pittsburgh At Pittsburgh

Abstract Text:
This study proposes to perform a clinical-metabolic-neuropathological correlation in **dementia**, in particular, primary degenerative **dementia** of the **Alzheimer** type (AD). We will use clinical data on behavior, mood, function, and cognition obtained in the year preceding death as markers of severity. Proton nuclear **magnetic resonance spectroscopy** (1/H **MRS**) will be used to analyze 6 brain areas obtained at autopsy from 75 **Alzheimer's disease** (AD), 25 controls, and 15 non-AD demented controls over 5 years. The first goal is to broaden the metabolic understanding of AD and to delineate clinical-metabolic-neuropathological correlations in a way that may provide insights into the timing of pathogenetic events over the course of this dementing illness. The second goal is to provide a detailed in vitro database for future extensions of this study into 1/H **MRS** studies of living patients with AD. No such detailed database currently exists. The metabolites measurable by 1/H MRS include N-acetyl-L-aspartate (NAA), L-glutamate, GABA, glutamine, myo-inositol, choline- containing compounds, creative and others. NAA is important because it is a putative neuronal marker easily detected by **in vitro** and **in vivo** 1/H **MRS** and can give an estimate of neuronal survival. Much like senile plaques and **neurofibrillary tangles**, NAA can be considered a new candidate marker of the neuropathological severity of **dementia**. The excitatory and inhibitory

amino acids also play key roles in excitotoxic theories of several **dementias**. The choline-containing compounds include a phosphodiester which is a product of membrane degradation. In addition to determining differences between AD and control, demented non-AD brains will be examined to determine the **specificity** of the changes for AD. Clinical-metabolic and metabolic-neuropathologic correlations to NAA, **senile plaques**, and **neurofibrillary tangles** will be done in an attempt to determine which changes represent early, potentially causative, events and which changes are more likely secondary effects of neurodegeneration. In addition, a separately funded study will be analyzing the tissue by 31/P **MRS** and the levels of the membrane metabolites, phosphomonoesters and phosphodiesters, will be available for correlative studies as well. We hypothesize that markers of membrane proliferation and neuronal inhibition will be elevated early in the disease and decreased at later stages. In contrast, markers of membrane degeneration and excitotoxicity will be elevated at later stages. Preliminary results suggest that the i**n vitro** 1/H **MRS** studies proposed in this application could provide information that is valuable in both a diagnostic and pathophysiologic sense and be readily extended to non-invasive, longitudinal studies of living patients which could aid in monitoring the course of the illness and tracking efficacy of experimental therapies.

The 8,236,282 and 8,691,185 patents

The 8,236,282 and 8,691,185 patents have the same three inventors (Klunk, Mathis and Wang), title and abstract, with somewhat different claims. The inventions involve compositions and methods of preparing benzothiazole derivatives, for the detection and diagnosis of diseases characterized by amyloid deposits. The priority date for both patents is August 22, 2003. The filing dates were September 30, 2009 and July 12, 2012.

Table 4 lists four NIH-funded projects by the University of Pittsburgh from 2001 to 2002 that list William Klunk as the Principal Investigator.

Table 4: NIH-Funded Projects to the University of Pittsburgh from Fiscal Years 2001 to 2002 Listing William Klunk as PI

Project Number	Title	FY	Agency	Amount
1K02AG001039 01A1	PET IMAGING PROBES FOR AMYLOID IN ALZHEIMERS AND AGING	2001	NIA	$97,686
1R01AG020226 01	PET TRACERS TO MONITOR VACCINE AND IMMUNE THERAPY FOR AD	2001	NIA	$366,936
5K02AG001039 02	PET IMAGING PROBES FOR AMYLOID IN ALZHEIMERS AND AGING	2002	NIA	$97,686
5R01AG020226 02	PET TRACERS TO MONITOR VACCINE AND IMMUNE THERAPY FOR AD	2002	NIA	$353,050

The budget end date for project 5R01AG020226-02 was July 31, 2003, less than two months before the priority date for the 8,236,282 and 8,691,185 patents, and right before the filing of the 7,270,800 and 7,351,401 patents.

The abstract for that grant reads as follows:

Project Number: 5R01AG020226-02
Contact PI / Project Leader: Klunk, William E
Title: PET Tracers To Monitor Vaccine And Immune Therapy For AD
Awardee Organization: University Of Pittsburgh At Pittsburgh

Abstract Text:
DESCRIPTION (provided by the applicant): The deposition of beta-sheet fibrils in **Alzheimer's disease (AD)** brain has been hypothesized to be the primary cause of this devastating neurodegenerative disease. These deposits include the **amyloid-beta** (Abeta) protein in **plaques** and vascular amyloid and hyper-phosphorylated tau protein in neurofibrillary tangles, dystrophic neurites and neuropil threads. Despite the presence of this characteristic neuropathology and its critical importance in the pathophysiology of the disease, no non-invasive technique has been validated to assess the presence of these deposits in living patients. The absence of such a technique hinders early and presymptomatic diagnosis and will severely hinder the development of immune therapies aimed at prevention or reversal of beta-sheet fibril deposition. Over the past decade, our laboratory has worked to develop an in vivo **beta-sheet amyloid** fibril imaging agent. This work has resulted in a promising lead agent, [N-methyl-11C]2(-4'-methylaminophenyl-**benzothiazole** (or [11C]BTA-1) which: 1) readily enters and clears from normal rodent and baboon brain; 2) binds to synthetic Abeta with nanomolar affinity; 3) specifically stains **plaques** and **tangles** in post-mortem AD brain; 4) binds to homogenates of post-mortem AD brain frontal cortex at >10-fold higher levels than aged control brain and non-AD demented brain samples, but shows no increased **binding** in AD **cerebellum**; and 5) shows no evidence of acute toxicity in preliminary studies. Furthermore, preliminary in vivo studies using APP transgenic mice and low resolution **PET scanning** show increased accumulation in the transgenic mice. In this study, we propose to validate the use of [11C]BTA-1 for in vivo **amyloid imaging** in PS/APP transgenic mice using a small animal microPET scanner. We will correlate in vivo results with: 1) quantitative immunohistochemical and histochemical measures of amyloid deposition; 2) Abeta ELISA; and 3) ex-vivo [11C]**BTA-1** levels and post-mortem [3H]**BTA-1** binding. We will show feasibility of longitudinal studies of the [11C]BTA-1/microPET technique in PS/APP mice and apply the technique to study an immune therapy protocol in these mice. Our goal is to provide a tool for use by investigators developing improved immune therapy protocols in transgenic mice, thus speeding progress in this area. However, because all of the techniques developed in this proposal apply directly to human studies, completion of this study will greatly speed the development of this technology for use in human studies of anti-amyloid therapies (immune therapy and secretase inhibitor therapies).

Description of the 7,270,800; 7,351,401; 8,236,282 and 8,691,185 patents

Thioflavin T is a benzothiazole compound, a fluorescent marker or a dye, that is used for the visualization and quantification of amyloid (misfolded protein aggregates found in the brains of patients diagnosed with Alzheimer's disease). Amyloids are made up of beta sheet fibrils or structures. The binding of Thioflavin T compounds to the amyloids' beta sheets displays a major increase in fluorescence intensity, allowing quantification of amyloids and diagnosis.[5]

In 2008, two of the patents' inventors, Klunk and Mathis, published a paper in the *Journal of Alzheimer Disease and Associated Disorders*, titled "Whatever happened to Pittsburgh Compound-A?"[6] The paper provides an overview of research undertaken in order to obtain the desired and most effective thioflavin derivative for the diagnosis of Alzheimer's disease. The following statements were provided:

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[5] (2010). Biancalana M; Koide S. "Molecular mechanism of Thioflavin-T binding to amyloid fibrils" *Biochim Biophys Acta*. 1804(7):1405-12.

[6] (2008). Klunk WE; Mathis CA. "Whatever happened to Pittsburgh Compound-A?" *Alzheimer Dis Assoc Disord*. 22(3):198-203.

> ". . . Pittsburgh Compound-A (PiA) represents one of the early thioflavin-T derivatives made in our amyloid-imaging tracer development program at the University of Pittsburgh.
>
> . . . For more than a decade, we struggled with manipulating the Congo red pharmacophore into a suitable positron emission tomography (PET) amyloid tracer with only limited success. This was primarily a result of the poor brain entry of this class of compounds.
>
> . . . The transition away from the Congo red derivatives such as the X-series began in November 1999. From that time through our present work with fluorine-18–labeled PiB derivatives, we have synthesized and tested over 350 thioflavin-T derivatives.
>
> . . . BTA-1 (PiA) was the seventh of the thioflavin-T derivatives and was first tested with in vitro binding studies and ex vivo mouse brain entry studies in April 2000, just 5 months into our thioflavin-T exploration program.
>
> . . . It is worth noting that we began the approval process for human studies simultaneously in Sweden and in the United States in 2001, understanding that it would take longer to begin our studies in Pittsburgh than it would to begin the Uppsala arm of this study. That process included toxicologic evaluation of the lead compound funded by a special National Institute on Aging (NIA) mechanism (NIA contract, N01- AG-9-2117).
>
> . . . NIA had already approved funding for toxicologic evaluation of Pittsburgh Compound-A, when the suggestion came up at our weekly chemistry meeting something to the effect of, "I've been looking at the data and thinking, and I don't think BTA-1 is the best compound. I think we should go with 6-OH-BTA-1 [the original name for PiB], because it is cleared from normal brain much better." It should not be surprising that this suggestion was initially met with a degree of inertia on both sides of the Atlantic.
>
> . . . PiB was the 23rd compound synthesized and tested in our thioflavin-T program in July 2000, so it had been on the (lab)books for more than a year before the first human study. The affinities of Pittsburgh Compound-A and PiB were never convincingly different in binding studies using Aβ fibrils or AD brain homogenates, but the more rapid clearance of PiB from normal animal brain was evident very early on.
>
> . . . The case was made as follows: when compared with several other proven dopamine and serotonin neuroreceptor radiotracers on "level ground," PiB fit the profile of a good tracer and Pittsburgh Compound-A did not."

The research paper further discloses how the correct thioflavin derivatives (PiA and PiB) were derived for the diagnosis of Alzheimer's disease, and notes some of the relevant time periods.

The following statements were made regarding funding:

> "Funding support for portions of the development program was provided by grants from The National Institutes of Health (R01 AG018402, P50 AG005133, K02 AG001039, R01 AG020226, R01 MH070729, K01 MH001976, R37 AG025516, P01 AG025204), the Alzheimer's Association (TLL-01-3381), GE Healthcare and the US Department of Energy (DE-FD02-03 ER63590)."

With the exception of grants R01 MH070729 and K01 MH001976 (PI Julie Price), all the other grants listed identified either William Klunk or Chester Mathis as the Principal Investigators.

Grant R01 AG018402

Using the NIH RePORTER database, we searched for the grant R01 AG018402. There were eight projects funded under grant R01 AG018402, where Chester Mathis was the Principal Investigator, from 2001 to 2010. The organization receiving the funding was the University of Pittsburgh.

Table 5: The Eight R01 AG018402 Projects Listing Chester Mathis as the PI and the University of Pittsburgh as the Institution

Project	Project Title	FY	Total Cost
1R01AG018402-01A1	AMYLOID IMAGING AGENTS FOR POSITRON EMISSION TOMOGRAPHY	2001	*$350,525*
5R01AG018402-02	AMYLOID IMAGING AGENTS FOR POSITRON EMISSION TOMOGRAPHY	2002	*$349,224*
5R01AG018402-03	AMYLOID IMAGING AGENTS FOR POSITRON EMISSION TOMOGRAPHY	2003	*$347,922*
5R01AG018402-04	AMYLOID IMAGING AGENTS FOR POSITRON EMISSION TOMOGRAPHY	2004	*$346,619*
2R01AG018402-05	AMYLOID IMAGING AGENTS FOR POSITION EMISSION TOMOGRAPHY	2007	*$339,851*
5R01AG018402-06	AMYLOID IMAGING AGENTS FOR POSITION EMISSION TOMOGRAPHY	2008	*$376,408*
5R01AG018402-07	AMYLOID IMAGING AGENTS FOR POSITION EMISSION TOMOGRAPHY	2009	*$394,437*

5R01AG018402-08	AMYLOID IMAGING AGENTS FOR POSITION EMISSION TOMOGRAPHY	2010	*$357,159*

Grant P50 AG005133

Using the NIH RePORTER database, we searched for the grant P50 AG005133. There were ten sub-projects funded under grant P50 AG005133, where William Klunk was the Principal Investigator, from 2005 to 2014.The organization receiving the funding was the University of Pittsburgh.

Table 6: The Ten P50 AG005133 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution

Project	Project Title	FY	Total Cost
2P50AG005133-22	NATURAL HISTORY OF AMYLOID DEPOSITION IN FAMILIAL AD	2005	*$185,625*
5P50AG005133-23	NATURAL HISTORY OF AMYLOID DEPOSITION IN FAMILIAL AD	2006	*$128,746*
5P50AG005133-24	NATURAL HISTORY OF AMYLOID DEPOSITION IN FAMILIAL ALZHEIMERS DISEASE	2007	*$214,077*
5P50AG005133-25	NATURAL HISTORY OF AMYLOID DEPOSITION IN FAMILIAL ALZHEIMERS DISEASE	2008	*$215,088*
5P50AG005133-26	NATURAL HISTORY OF AMYLOID DEPOSITION IN FAMILIAL ALZHEIMERS DISEASE	2009	*$221,371*
2P50AG005133-27	NATURAL HISTORY OF AMYLOID DEPOSITION FAMILIAL AD	2010	*$171,025*
5P50AG005133-28	NATURAL HISTORY OF AMYLOID DEPOSITION FAMILIAL AD	2011	*$199,286*
5P50AG005133-29	NATURAL HISTORY OF AMYLOID DEPOSITION FAMILIAL AD	2012	*$182,113*
5P50AG005133-30	NATURAL HISTORY OF AMYLOID DEPOSITION FAMILIAL AD	2013	*$170,365*
5P50AG005133-31	NATURAL HISTORY OF AMYLOID DEPOSITION FAMILIAL AD	2014	*$182,280*

Grant K02 AG001039

Using the NIH RePORTER database, we searched for the grant K02 AG001039. There were five projects funded under grant K02 AG001039, where William Klunk was the Principal Investigator, from 2001 to 2005. The organization receiving the funding was the University of Pittsburgh.

Table 7: The Five K02 AG001039 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution

Project	Project Title	FY	Total Cost
1K02AG001039-01A1	PET IMAGING PROBES FOR AMYLOID IN ALZHEIMERS AND AGING	2001	*$97,686*
5K02AG001039-02	PET IMAGING PROBES FOR AMYLOID IN ALZHEIMERS AND AGING	2002	*$97,686*
5K02AG001039-03	PET IMAGING PROBES FOR AMYLOID IN ALZHEIMERS AND AGING	2003	*$97,686*
5K02AG001039-04	PET IMAGING PROBES FOR AMYLOID IN ALZHEIMERS AND AGING	2004	*$97,686*
5K02AG001039-05	PET IMAGING PROBES FOR AMYLOID IN ALZHEIMERS AND AGING	2005	*$97,686*

Grant R01 AG020226

Using the NIH RePORTER database, we searched for the grant R01 AG020226. There were five projects funded under grant R01 AG020226, where William Klunk was the Principal Investigator, from 2001 to 2005. The organization receiving the funding was the University of Pittsburgh.

Table 8: The Five R01 AG020226 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution

Project	Project Title	FY	Total Cost
1R01AG020226-01	PET TRACERS TO MONITOR VACCINE AND IMMUNE THERAPY FOR AD	2001	*$366,936*

5R01AG020226-02	PET TRACERS TO MONITOR VACCINE AND IMMUNE THERAPY FOR AD	2002	*$353,050*
5R01AG020226-03	PET TRACERS TO MONITOR VACCINE AND IMMUNE THERAPY FOR AD	2003	*$353,050*
5R01AG020226-04	PET TRACERS TO MONITOR VACCINE AND IMMUNE THERAPY FOR AD	2004	*$353,050*
5R01AG020226-05	PET TRACERS TO MONITOR VACCINE AND IMMUNE THERAPY FOR AD	2005	*$353,050*

Grant R37 AG025516

Using the NIH RePORTER database, we searched for the grant R37 AG025516. There were eleven projects funded under grant R37 AG025516, where William Klunk was the Principal Investigator, from 2005 to 2014. The organization receiving the funding was the University of Pittsburgh.

Table 9: The Eleven R37 AG025516 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution

Project	Project Title	FY	Total Cost
1R37AG025516-01	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2005	*$430,155*
5R37AG025516-02	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2006	*$459,594*
5R37AG025516-03	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2007	*$459,409*
5R37AG025516-04	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2008	*$449,361*
3R37AG025516-05S1	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2009	*$5,000*

5R37AG025516-05	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2009	*$362,933*
4R37AG025516-06	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2010	*$473,345*
5R37AG025516-07	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2011	*$481,954*
5R37AG025516-08	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2012	*$480,423*
5R37AG025516-09	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2013	*$441,934*
5R37AG025516-10	AMYLOID PATHOLOGY AND COGNITION IN NORMAL ELDERLY	2014	*$227,443*

Grant P01 AG025204

Using the NIH RePORTER database, we searched for the grant P01 AG025204. There were 36 projects funded under grant P01 AG025204, where William Klunk was the Principal Investigator, from 2005 to 2018. The organization receiving the funding was the University of Pittsburgh.

Of interest are the nineteen grants listed from years 2005-2012, prior to the filing dates for two of the patents.

Table 10: The Nineteen P01 AG025204 Projects Listing William Klunk as the PI and the University of Pittsburgh as the Institution

Project	Project Title	FY	Total Cost
1P01AG025204-01	CROSS-SECTIONAL ASSESSMENT OF IN VIVO AMYLOID IN MCI AND AD	2005	*$157,425*
5P01AG025204-02	CROSS-SECTIONAL ASSESSMENT OF IN VIVO AMYLOID IN MCI AND AD	2006	*$172,602*
5P01AG025204-03	CROSS-SECTIONAL ASSESSMENT OF IN VIVO AMYLOID IN MCI AND AD	2007	*$298,271*
3P01AG025204-04S1	IN VIVOPIB PET AMYLOID IMAGING: NORMALS, MCI & DEMENTIA	2008	*$142,645*

5P01AG025204-04	CROSS-SECTIONAL ASSESSMENT OF IN VIVO AMYLOID IN MCI AND AD	2008	*$259,127*
5P01AG025204-04	IN VIVOPIB PET AMYLOID IMAGING: NORMALS, MCI & DEMENTIA	2008	*$1,031,916*
5P01AG025204-05	CROSS-SECTIONAL ASSESSMENT OF IN VIVO AMYLOID IN MCI AND AD	2009	*$360,047*
5P01AG025204-05	IN VIVOPIB PET AMYLOID IMAGING: NORMALS, MCI & DEMENTIA	2009	*$1,151,713*
2P01AG025204-06	ADMINISTRATIVE CORE	2010	*$129,363*
2P01AG0252040-06	MODULATORS OF COGNITIVE TRANSIFION FROM MCI TO AD	2010	*$301,836*
2P01AG025204-06	IN VIVO PIB PET AMYLOID IMAGING: NORMALS, MCI & DEMENTIA	2010	*$1,538,583*
5P01AG025204-07	ADMINISTRATIVE CORE	2011	*$126,512*
5P01AG025204-07	MODULATORS OF COGNITIVE TRANSIFION FROM MCI TO AD	2011	*$346,486*
5P01AG025204-07	QUANTITATIVE NEUROPATHOLOGICAL CORRELATES OF IN VIVO PIB RETENTION	2011	*$292,634*
5P01AG025204-07	IN VIVO PIB PET AMYLOID IMAGING: NORMALS, MCI & DEMENTIA	2011	*$1,482,584*
5P01AG025204-08	ADMINISTRATIVE CORE	2012	*$126,424*
5P01AG025204-08	MODULATORS OF COGNITIVE TRANSIFION FROM MCI TO AD	2012	*$337,923*
5P01AG025204-08	QUANTITATIVE NEUROPATHOLOGICAL CORRELATES OF IN VIVO PIB RETENTION	2012	*$287,620*
5P01AG025204-08	IN VIVO PIB PET AMYLOID IMAGING: NORMALS, MCI & DEMENTIA	2012	*$1,420,069*

Additional Notes on Research Grants from the National Institutes of Health

NIH Grants to William Klunk Cited in a 2003 Paper

In 2003, the patents' inventors, Klunk, Mathis and Wang, published a paper in the journal *Proceedings of the National Academy of Sciences of the United States of America* along with seven co-authors, titled "Four-dimensional multiphoton imaging of brain entry, amyloid binding, and clearance of an amyloid-beta ligand in transgenic mice."[7] The paper made disclosures regarding funding, including NIH grants to Mathis and Klunk:

> "...This work supported by National Institutes of Health Grants AG08487 (to B.T.H.), AG18402 (**to C.A.M.**), AG01039 (**to W.E.K.**), AG20226 (**to W.E.K.**), AG15453 (to B.T.H.), EB00768 (to B.J.B.), and AG020570 (to B.J.B.), an Alzheimer Association Pioneer Award (to B.T.H.), Alzheimer Association Grants IIRG-95-076 (to W.E.K.), TLL-01-3381 (to W.E.K.), and NIRG-00-2355 (to Y.W.), and Institute for the Study of Aging/American Federation for Aging Research Grant 210304 (to Y.W.)."

The abstract for Bacskai *et al.* 2003 reads as follows:

> "The lack of a specific biomarker makes preclinical diagnosis of **Alzheimer's disease** (AD) impossible, and it precludes assessment of therapies aimed at preventing or reversing the course of the disease. The development of a tool that enables direct, quantitative detection of the **amyloid-beta deposits** found in the disease would provide an excellent biomarker. This article demonstrates the real-time biodistribution kinetics of an imaging agent in transgenic mouse models of **AD**. Using multiphoton microscopy, **Pittsburgh compound B (PIB)** was imaged with sub-μm resolution in the brains of living transgenic mice during peripheral administration. **PIB** entered the brain quickly and labeled **amyloid deposits** within minutes. The nonspecific **binding** was cleared rapidly, whereas specific labeling was prolonged. WT mice showed rapid brain entry and clearance of **PIB** without any binding. These results demonstrate that the compound **PIB** has the properties required for a good amyloid-imaging agent in humans with or at risk for **AD**."

NIH Grants to Chester Mathis Cited in a 2004 Paper

In 2004, the patents inventors, Klunk, Mathis and Wang, published a paper in the journal *Annals of Neurology* along with eighteen co-authors, titled "Imaging brain amyloid in Alzheimer's disease with Pittsburgh Compound-B."[8] PubMed provides the following information on the grant support:

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[7] (2003). Bacskai BJ; Hickey GA; Skoch J; Kajdasz ST; Wang Y; Huang GF; Mathis CA; Klunk WE; Hyman BT. "Four-dimensional multiphoton imaging of brain entry, amyloid binding, and clearance of an amyloid-beta ligand in transgenic mice." *Proc Natl Acad Sci U S A.* 100(21):12462-7.

> "Grant support
> AG 01039/AG/NIA NIH HHS/United States
> **AG 05133/AG/NIA NIH HHS/United States**
> **AG 18402/AG/NIA NIH HHS/United States**
> AG 20226/AG/NIA NIH HHS/United States"

The abstract for Klunk *et al.* 2004 reads as follows:

> "This report describes the first human study of a novel **amyloid-imaging positron emission tomography (PET)** tracer, termed **Pittsburgh Compound-B (PIB)**, in 16 patients with diagnosed mild **AD** and 9 controls. Compared with controls, **AD** patients typically showed marked retention of **PIB** in areas of association cortex known to contain large amounts of amyloid deposits in **AD**. In the **AD** patient group, **PIB** retention was increased most prominently in frontal cortex (1.94-fold, p = 0.0001). Large increases also were observed in parietal (1.71-fold, p = 0.0002), temporal (1.52-fold, p = 0.002), and occipital (1.54-fold, p = 0.002) cortex and the striatum (1.76-fold, p = 0.0001). **PIB** retention was equivalent in AD patients and controls in areas known to be relatively unaffected by **amyloid** deposition (such as subcortical white matter, pons, and cerebellum). Studies in three young (21 years) and six older healthy controls (69.5 ± 11 years) showed low PIB retention in cortical areas and no significant group differences between young and older controls. In cortical areas, PIB retention correlated inversely with cerebral glucose metabolism determined with 18F-fluorodeoxyglucose. This relationship was most robust in the parietal cortex (r = −0.72; p = 0.0001). The results suggest that **PET** imaging with the novel tracer, PIB, can provide quantitative information on **amyloid deposits** in living subjects.

NIH Grants to Yanming Wang

In 2004, the patents' inventors, Klunk, Mathis and Wang, published a paper in the *Journal of Molecular Neuroscience* along with four co-authors, titled "development of a PET/SPECT agent for amyloid imaging in Alzheimer's disease."[9] PubMed provides the following information on the grant support:

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[8] (2004). Klunk WE; Engler H; Nordberg A; Wang Y; Blomqvist G; Holt DP; Bergström M; Savitcheva I; Huang GF; Estrada S; Ausén B; Debnath ML; Barletta J; Price JC; Sandell J; Lopresti BJ; Wall A; Koivisto P; Antoni G; Mathis CA; Långström B. "Imaging brain amyloid in Alzheimer's disease with Pittsburgh Compound-B." *Ann Neurol.* 55(3):306-19.

[9] (2004). Wang Y; Klunk WE; Debnath ML; Huang GF; Holt DP; Shao L; Mathis CA. "Development of a PET/SPECT agent for amyloid imaging in Alzheimer's disease." *J Mol Neurosci.* 24(1):55-62.

> "Grant support
> AG01039/AG/NIA NIH HHS/United States
> AG05133/AG/NIA NIH HHS/United States
> AG18402/AG/NIA NIH HHS/United States
> AG20226/AG/NIA NIH HHS/United States
> **AG22048-01A1/AG/NIA NIH HHS/United States**"

The abstract for Wang *et al.* 2004 reads as follows:

> "In the search for a cure for **Alzheimer's disease (AD)**, efforts have been focused on preventing or reversing **amyloid deposition** in the **brain**. Efficacy evaluation of these antiamyloid therapies would greatly benefit from development of a tool for the **in vivo** detection and quantitation of **amyloid deposits** in the brain. Toward this goal, we have developed a series of **benzothiazole derivatives** as **amyloid-imaging agents** for **positron emission tomography (PET)**. To extend the potential of these **amyloid-imaging agents** for routine clinical studies, we also set out to develop iodinated **benzothiazole derivatives** that could be used as dual agents for either PET or the complementary s**ingle photon emission computed tomography (SPECT)**. Such dual agents would permit **PET** or **SPECT** studies using radiotracers with the same chemical identity but labeled with different radionuclides. This would facilitate the validation of clinical **SPECT** studies, based on quantitative **PET** studies. In this work we report the synthesis and biological evaluation of a potent, selective, and brain-permeable benzothiazole compound, 2-(3'-iodo-4'-methylaminophenyl)-6-hydroxy-benzothialzole, termed 6-OH-BTA-1-3'-I (4), which can be **radiolabeled** with either positron-emitting carbon-11 or single photon-emitting iodine-125/iodine-123. The synthesis and radiolabeling of [125I]4 or [11C]4 were achieved through direct iodination with sodium [125I]iodide in the presence of chloramine T or through radiomethylation with [11C]CH3I. **In vitro amyloid binding** assays indicated that [125I]4 bound to **amyloid deposits** in a saturable manner and exhibited affinities in the nanomolar concentration range. Binding studies of [125I]4 to postmortem human brain homogenates also showed preference of binding to frontal cortex in the **AD** homogenates relative to age-matched control **homogenates** or **cerebellum** from either **AD** or control. **In vivo** pharmacokinetic studies in normal mice following iv injection of [11C]4 indicated that the **radioligand** entered the **brain** readily at early time points and cleared from the **brain** rapidly at later time points with a 2- to 30-min ratio >3. These results suggest that the new radioiodinated **benzothiazole ligand** might be useful as a surrogate marker for the in vivo quantitation of **amyloid deposition** in human brain for use with either **PET** or **SPECT**."

According to the NIH RePORTER database, Yanming Wang received a total of $602,463 to support five projects that mention amyloid and involve diagnostics tests for dementia and/or Alzheimer's disease.

Table 11: Five NIH Grants to Yanming Wang from 2003-2007 Mentioning Amyloid-based Screening for Alzheimer's and Dementia

Grant Number	Title	Budget Start Date	Budget End Date	Agency
1K25AG022048-01A1	QUANTITATIVE IMAGING OF AMYLOID DEPOSITS IN AD AND AGING	9/30/2003	8/31/2004	NIA
7K25AG022048-02	QUANTITATIVE IMAGING OF AMYLOID DEPOSITS IN AD AND AGING	9/15/2004	8/31/2005	NIA
5K25AG022048-03	QUANTITATIVE IMAGING OF AMYLOID DEPOSITS IN AD AND AGING	9/1/2005	7/14/2006	NIA
7K25AG022048-04	QUANTITATIVE IMAGING OF AMYLOID DEPOSITS IN AD AND AGING	9/1/2006	8/31/2007	NIA
5K25AG022048-05	QUANTITATIVE IMAGING OF AMYLOID DEPOSITS IN AD AND AGING	9/1/2007	8/31/2008	NIA

Why the Wang Grants are Related to the Inventions

The abstracts given for the grants are as follows:

The Abstract for the Wang Amyloid Grants listed in Table 11

1K25AG022048-01A1, 7K25AG022048-02, 5K25AG022048-03, 7K25AG022048-04 and 5K25AG022048-05

DESCRIPTION (provided by applicant): In this application for a Mentored Quantitative Research Career Development Award (K25), the candidate's research and career development plans are described. The project is designed to customize the educational and research activities for the candidate to achieve two major goals. The immediate goal is for the candidate to continue his research in **amyloid imaging** in **Alzheimer's disease** and aging. The long-term goal is for the candidate to acquire advanced biomedical research skills and develop as an independent researcher in aging-related biomedical imaging. To achieve these goals, the candidate will obtain further trainings in neuroscience, biostatistics, pharmacology, and pharmacokinetics as well as in responsible conduct of biomedical and clinical research. He will also acquire related knowledge through journal clubs, research seminars, lectures, and conferences, and through interaction with other investigators and trainees. The practical skills in biomedical imaging will primarily be obtained through the proposed microPET studies under the guidance of Drs. Mathis and Klunk at the University of Pittsburgh. In this proposed research, the candidate plans to use microPET to evaluate amyloid-imaging agents in transgenic mice models of **amyloid deposition**. This will allow us for the first time to evaluate the in vivo binding specificity and pharmacokinetic profiles of lead compounds in a CNS model that mimics the future human studies. Therefore, this project will satisfy the following specific aims: 1) rationally design and synthesize a selected array of amyloid-binding agents; 2) evaluate the new compounds for in vitro binding affinity and specificity for amyloid deposits; 3) evaluate selected compounds in ex vivo studies of brain entry, crearance; and metabolism in normal control mice with no amyloid deposits in the brain; 4) use microPET to assess the in vivo properties of selected compounds in amyloid-containing transgenic mouse models to determine **in vivo** binding specificity and detailed pharmacokinetic profiles. The overall goal of our research is to identify potent, selective, and brain permeable amyloid probes suitable for in vivo human studies.

The patents listed above in Table 2 provide several key terms/words that appear to be the subject matter of the grants listed in Table 11, including, to mention a few:

- These facts have little implications for **amyloid imaging** studies in which an extremely minute amount of the high specific activity radiolabelled dye would be directly injected into the blood stream. (PAGE 4, PATENT 7,351,401)
- The disease states or maladies include but are not limited to **Alzheimer's Disease**, familial **Alzheimer's Disease**, Down's Syndrome and homozygotes for the apolipoprotein E4 allele. (ABSTRACT, PATENT 7270800)
- **In Vivo** Baboon Imaging Studies (PAGE 17, PATENT 8,236,282)
- In allowing the temporal sequence of **amyloid deposition** to be followed, the inventive compound may further be used to correlate **amyloid deposition** with the onset of clinical symptoms associated with a disease, disorder or condition. (PAGE 5, PATENT 8,236,282)
- This study reflects **brain entry** and clearance from normal brain tissue. (PAGE 16, PATENT 8,236,282)

The Vizamyl Prices

Vizamyl injection is available in 10 or 30 mL multi-dose glass vial at a strength of 150 MBq/mL (4.05 mCi/mL). The price of 1 vial (5 mCi) is approximately $28,000.[10]

Requested Remedies for Non-disclosure

The Bayh-Dole Act and federal regulations and guidelines obligate contractors to disclose government rights in subject inventions, including via: (1) a requirement to disclose within a reasonable time that federal funding contributed to a subject invention; (2) contractual requirements for disclosure; and (3) required language to be inserted in patent applications and the patents, stating the role of federal funding and the government's rights.

After establishing a failure by the patent holder to disclose the federal funding, an agency may choose to require the patent holders to provide a disclosure to iEdison and to submit a Certificate of Correction to the United States Patent and Trademark (UPSPTO). The agency also has consequential remedies. In particular, a failure to disclose subject inventions pursuant to 35 U.S.C. § 202(c)(1) permits the federal government to "receive title to any subject invention not disclosed to it within such time."

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[10] https://www.rxgo.com/drug/vizamyl-coupon

The disclosure itself is an acknowledgement that the federal government has certain rights in the patents, and that the patent holder has certain obligations. When federal funding is involved, the patent owner has an obligation to manufacture the invention substantially within the United States and to make the invention "available to the public on reasonable terms." The federal government possesses a worldwide royalty-free right to use the patent, and may grant a compulsory license to the patent under the Bayh-Dole march-In provisions of 35 U.S.C. § 203(a).

The failure to make a timely disclosure of the federal funding should be seen as an attempt to evade these responsibilities and as a denial of the government's rights in the invention.

KEI recommends that the federal government take title to the invention, since the lesser remedy of requiring late disclosure has not, in the past, provided an adequate incentive for patent holders to comply with the disclosure obligations.

For a more detailed discussion of the specific statutory, regulatory and contractual obligations to disclose federal funding in patented inventions, and the remedies when funding is not disclosed, see: KEI Briefing Note 2018:1.

ANNEX 1: Select News Reports and Other Background on Vizamyl

About Alzheimer's disease. Alzheimer's Association.

2014. Scott Lerman. GE Healthcare Announces European Union Approval of VIZAMYL™ (Flutemetamol (18F) Solution for Injection) for PET Imaging of Beta Amyloid Plaque in Suspected Alzheimer's Disease. *Business Wire*. September 1, 2014.

2015. Lauren Dubinsky. GE's Vizamyl improves diagnostic confidence for early-onset dementia. *DOTmed*. July 22, 2015.

ANNEX 2: NIH Grants to the University of Pittsburgh with William E. Klunk Listed as Principal Investigator, with Search Term "Amyloid"

The search term for NIH RePORTER database: "Text Search: amyloid (and); Search in: Projects, AdminIC: All; Principal Investigator / Project Leader: Klunk; William; Fiscal Year: All Fiscal Years."

Project Number	Project Title	Fiscal Year	FY Cost
1F32AG005443-01	Molecular Probes For Alzheimer Beta-amyloid Protein	1988	$27,000
5F32AG005443-02	Molecular Probes For Alzheimer Beta-amyloid Protein	1989	$31,750
1K02AG001039-01A1	Pet Imaging Probes For Amyloid In Alzheimers And Aging	2001	$97,686
1R01AG020226-01	Pet Tracers To Monitor Vaccine And Immune Therapy For AD	2001	$366,936
5K02AG001039-02	Pet Imaging Probes For Amyloid In Alzheimers And Aging	2002	$97,686
5R01AG020226-02	Pet Tracers To Monitor Vaccine And Immune Therapy For AD	2002	$353,050
5K02AG001039-03	Pet Imaging Probes For Amyloid In Alzheimers And Aging	2003	$97,686
5R01AG020226-03	Pet Tracers To Monitor Vaccine And Immune Therapy For AD	2003	$353,050
5R01AG020226-04	Pet Tracers To Monitor Vaccine And Immune Therapy For AD	2004	$353,050
5K02AG001039-04	Pet Imaging Probes For Amyloid In Alzheimers And Aging	2004	$97,686
5K02AG001039-05	Pet Imaging Probes For Amyloid In Alzheimers And Aging	2005	$97,686
1R37AG025516-01	Amyloid Pathology And Cognition In Normal Elderly	2005	$430,155
1P01AG025204-01	Cross-sectional Assessment Of In Vivo Amyloid In Mci And AD	2005	$157,425
2P50AG005133-22	Natural History Of Amyloid Deposition In Familial AD	2005	$185,625
5R01AG020226-05	Pet Tracers To Monitor Vaccine And Immune Therapy For AD	2005	$353,050
5P50AG005133-23	Natural History Of Amyloid Deposition In Familial AD	2006	$128,746
5P01AG025204-02	Cross-sectional Assessment Of In Vivo Amyloid In Mci And AD	2006	$172,602
1U01AG028526-01	Amyloid-lowering Small Molecule Ab-binding Agents In AD	2006	$459,078
5R37AG025516-02	Amyloid Pathology And Cognition In Normal Elderly	2006	$459,594
5P01AG025204-03	Cross-sectional Assessment Of In Vivo Amyloid In Mci And AD	2007	$298,271
5U01AG028526-02	Amyloid-lowering Small Molecule Ab-binding Agents In AD	2007	$450,738
5P50AG005133-24	Natural History Of Amyloid Deposition In Familial Alzheimers Disease	2007	$214,077
5R37AG025516-03	Amyloid Pathology And Cognition In Normal Elderly	2007	$459,409
5R37AG025516-04	Amyloid Pathology And Cognition In Normal Elderly	2008	$449,361
5P50AG005133-25	Natural History Of Amyloid Deposition In Familial Alzheimers Disease	2008	$215,088
3P01AG025204-04S1	In Vivopib Pet Amyloid Imaging: Normals; Mci & Dementia	2008	$142,645
5P01AG025204-04	In Vivopib Pet Amyloid Imaging: Normals; Mci & Dementia	2008	$1,031,916
5U01AG028526-03	Amyloid-lowering Small Molecule Ab-binding Agents In AD	2008	$454,087
5P01AG025204-04	Cross-sectional Assessment Of In Vivo Amyloid In Mci And AD	2008	$259,127

5P50AG005133-26	Natural History Of Amyloid Deposition In Familial Alzheimers Disease	2009	$221,371
5P01AG025204-05	In Vivopib Pet Amyloid Imaging: Normals; Mci & Dementia	2009	$1,151,713
5U01AG028526-04	Amyloid-lowering Small Molecule Ab-binding Agents In AD	2009	$466,821
5R37AG025516-05	Amyloid Pathology And Cognition In Normal Elderly	2009	$362,933
5P01AG025204-05	Cross-sectional Assessment Of In Vivo Amyloid In Mci And AD	2009	$360,047
3R37AG025516-05S1	Amyloid Pathology And Cognition In Normal Elderly	2009	$5,000
2P01AG025204-06	Modulators Of Cognitive Transifion From Mci To AD	2010	$301,836
4R37AG025516-06	Amyloid Pathology And Cognition In Normal Elderly	2010	$473,345
2P01AG025204-06	In Vivo Pib Pet Amyloid Imaging: Normals; Mci & Dementia	2010	$1,538,583
5U01AG028526-05	Amyloid-lowering Small Molecule Ab-binding Agents In AD	2010	$504,093
5P01AG025204-07	In Vivo Pib Pet Amyloid Imaging: Normals; Mci & Dementia	2011	$1,482,584
5R37AG025516-07	Amyloid Pathology And Cognition In Normal Elderly	2011	$481,954
5P50AG005133-28	Natural History Of Amyloid Deposition Familial Ad	2011	$199,286
5P50AG005133-29	Natural History Of Amyloid Deposition Familial Ad	2012	$182,113
5P01AG025204-08	Administrative Core	2012	$126,424
5P01AG025204-08	Modulators Of Cognitive Transifion From Mci To Ad	2012	$337,923
5P01AG025204-08	Quantitative Neuropathological Correlates Of In Vivo Pib Retention	2012	$287,620
5R37AG025516-08	Amyloid Pathology And Cognition In Normal Elderly	2012	$480,423
5P01AG025204-08	In Vivo Pib Pet Amyloid Imaging: Normals; Mci & Dementia	2012	$1,420,069
5R37AG025516-09	Amyloid Pathology And Cognition In Normal Elderly	2013	$441,934
5P01AG025204-09	Modulators Of Cognitive Transifion From Mci To Ad	2013	$267,813
5P01AG025204-09	Administrative Core	2013	$113,777
5P01AG025204-09	Quantitative Neuropathological Correlates Of In Vivo Pib Retention	2013	$274,558
5P01AG025204-09	In Vivo Pib Pet Amyloid Imaging: Normals; Mci & Dementia	2013	$1,295,247
5P50AG005133-30	Natural History Of Amyloid Deposition Familial Ad	2013	$170,365
2RF1AG025516-11	Amyloid Pathology And Cognition In Normal Elderly	2014	$2,701,818
5P01AG025204-10	Administrative Core	2014	$126,259
5P01AG025204-10	Modulators Of Cognitive Transifion From Mci To Ad	2014	$175,638
5P01AG025204-10	Quantitative Neuropathological Correlates Of In Vivo Pib Retention	2014	$286,635
5P01AG025204-10	In Vivo Pib Pet Amyloid Imaging: Normals; Mci & Dementia	2014	$1,146,355
5R37AG025516-10	Amyloid Pathology And Cognition In Normal Elderly	2014	$227,443
5P50AG005133-31	Natural History Of Amyloid Deposition Familial Ad	2014	$182,280

1U01AG051406-01	Neurodegeneration In Aging Down Syndrome (niad): A Longitudinal Study Of Cognition And Biomarkers Of Alzheimer's Disease	2015	$3,656,559
2P01AG025204-11A1	Imaging Pathophysiology In Aging And Neurodegeneration	2016	$1,998,101
3RF1AG025516-11S1	Amyloid Pathology And Cognition In Normal Elderly	2016	$782,946
5U01AG051406-02	Neurodegeneration In Aging Down Syndrome (niad): A Longitudinal Study Of Cognition And Biomarkers Of Alzheimer's Disease	2016	$3,556,865
3U01AG051406-03S1	Neurodegeneration In Aging Down Syndrome (niad): A Longitudinal Study Of Cognition And Biomarkers Of Alzheimer's Disease	2017	$158,939
5P01AG025204-12	Imaging Pathophysiology In Aging And Neurodegeneration	2017	$2,020,576
3U01AG051406-03S2	Neurodegeneration In Aging Down Syndrome (niad): A Longitudinal Study Of Cognition And Biomarkers Of Alzheimer's Disease	2017	$163,334
5U01AG051406-03	Neurodegeneration In Aging Down Syndrome (niad): A Longitudinal Study Of Cognition And Biomarkers Of Alzheimer's Disease	2017	$3,623,562

ANNEX 3: Eighteen Patents Assigned to the University of Pittsburgh that List William E. Klunk as the Inventor

Note: only one patent disclosed federal funding.

Patent Number	Title
9,833,458	Thioflavin derivatives for use in the antemortem diagnosis of Alzheimer's disease and in vivo imaging and prevention of amyloid deposition
9,808,541	Thioflavin derivatives for use in antemortem diagnosis of Alzheimer's disease and in vivo imaging and prevention of amyloid deposition
9,134,328	Methods of using benzothiazole derivative compounds and compositions
8,911,707	Thioflavin derivatives for use in antemortem diagnosis of alzheimer's disease and in vivo imaging and prevention of amyloid deposition
8,691,185	Benzothiazole derivative compounds, compositions and uses
8,580,229	Amyloid imaging as a surrogate marker for efficacy of anti-amyloid therapies

8,404,213	Thioflavin derivatives for use in antemortem diagnosis of Alzheimer's disease and in vivo imaging and prevention of amyloid deposition
8,343,457	Amyloid imaging as a surrogate marker for efficacy of anti-amyloid therapies
8,236,282	Benzothiazole derivative compounds, compositions and uses
8,147,798	Amyloid imaging as a surrogate marker for efficacy of anti-amyloid therapies
8,138,360	Isotopically-labeled benzofuran compounds as imaging agents for amyloidogenic proteins
7,854,920	Thioflavin derivatives for use in antemortem diagnosis of alzheimer's disease and in vivo imaging and prevention of amyloid deposition
7,351,401	Thioflavin derivatives for use in the antemortem diagnosis of Alzheimers disease and in vivo imaging and prevention of amyloid deposition
7,270,800	Thioflavin derivatives for use in antemortem diagnosis of Alzheimer's disease and in vivo imaging and prevention of amyloid deposition
6,417,178	Amyloid binding nitrogen-linked compounds for the antemortem diagnosis of alzheimer's disease, in vivo imaging and prevention of amyloid deposits
6,168,776	Alkyl, alkenyl and alkynyl Chrysamine G derivatives for the antemortem diagnosis of Alzheimer's disease and in vivo imaging and prevention of amyloid deposition
6,133,259	Alkyl, alkenyl and alkynyl chrysamine G derivatives for inhibition of cell degeneration and toxicity associated with amyloid deposition
6,1144,175	Compound for the antemortem diagnosis of Alzheimer's Disease and in vivo imaging and prevention of amyloid deposition

ANNEX 4: NIH Grants to the University of Pittsburgh with Chester A. Mathis Listed as Principal Investigator, with Search Term "Amyloid"

The search term for NIH RePORTER database: "Text Search: amyloid (and); Search in: Projects, AdminIC: All; Principal Investigator / Project Leader: Mathis; Chester; Fiscal Year: All Fiscal Years."

Project Number	Project Title	Agency	FY	FY Cost
1R01AG018402-01A1	Amyloid Imaging Agents For Positron Emission Tomography	NIA	2001	$350,525
5R01AG018402-02	Amyloid Imaging Agents For Positron Emission Tomography	NIA	2002	$349,224
5R01AG018402-03	Amyloid Imaging Agents For Positron Emission Tomography	NIA	2003	$347,922
5R01AG018402-04	Amyloid Imaging Agents For Positron Emission Tomography	NIA	2004	$346,619
2R01AG018402-05	Amyloid Imaging Agents For Position Emission Tomography	NIA	2007	$339,851
5R01AG018402-06	Amyloid Imaging Agents For Position Emission Tomography	NIA	2008	$376,408
5R01AG018402-07	Amyloid Imaging Agents For Position Emission Tomography	NIA	2009	$394,437
5R01AG018402-08	Amyloid Imaging Agents For Position Emission Tomography	NIA	2010	$357,159
1S10RR028324-01	Siemens Eclipse Hp Cyclotron For Pet Imaging Research	NCRR	2010	$2,688,777
2P50AG005133-32	Project 2: Pet Imaging Of Tau In Elderly Controls; Mci; And Ad	NIA	2015	$137,119
5P50AG005133-33	Project 2: Pet Imaging Of Tau In Elderly Controls; Mci; And Ad	NIA	2016	$137,119
5P50AG005133-34	Project 2: Pet Imaging Of Tau In Elderly Controls; Mci; And Ad	NIA	2017	$137,119

From: Mowatt, Michael (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB1EF7E2E54B4164AE34814574BDA638-MMOWATT]
Sent: 11/14/2017 8:44:37 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: RE: Response to 82 FRN 47537

Yep – thanks for the reminder! Crazy day.

Talk to you in the morning. Thanks for joining us!

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, November 14, 2017 3:43 PM
To: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>
Subject: RE: Response to 82 FRN 47537

You scheduled a meeting/call at 9:30 tomorrow. If the meeting is not long, I can also talk after the TDC call.

From: Mowatt, Michael (NIH/NIAID) [E]
Sent: Tuesday, November 14, 2017 3:41 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: FW: Response to 82 FRN 47537

I need to head out now; back tomorrow AM.

Can we talk tomorrow? After TDC noon call?

I've not heard from Barry Datlof.

From: Mowatt, Michael (NIH/NIAID) [E]
Sent: Tuesday, November 14, 2017 10:19 AM
To: Barry Datlof (barry.m.datlof.civ@mail.mil) <barry.m.datlof.civ@mail.mil>
Cc: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>
Subject: Response to 82 FRN 47537

Barry,

I hope all's well with you. b6 since last we spoke.

I don't know if you've been tracking our FRN, but KEI provided comments and posted a joint statement with MSF: https://keionline.org/node/2892.

I don't recall whether the Army responded to KEI, but I'd be interested in your perspectives. Can you spare a few minutes today or tomorrow for a catch up call with me and Mark Rohrbaugh?

Mike
Michael R. Mowatt, Ph.D.
Director, Technology Transfer and Intellectual Property Office

National Institute of Allergy and Infectious Diseases
National Institutes of Health

U.S. Department of Health and Human Services

+1 301 496 2644

NIH National Institute of Allergy and Infectious Diseases

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From: Joe Allen [jallen@allen-assoc.com]
Sent: 2/22/2017 3:24:13 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]
Subject: "Patents are destroying the soul of academic science"

FYI, with KEI's compulsory licensing meeting on Friday, the timing on this article is curious. Could just be serendipity, but wouldn't bet on it

-------- Forwarded Message --------
Subject:"Patents are destroying the soul of academic science"
Date: Wed, 22 Feb 2017 10:05:29 -0500
From: Joe Allen <jallen@allen-assoc.com>
To: Ashley Stevens <astevens@bu.edu>, ssususalka@autm.net <ssususalka@autm.net>, David Winwood <david.winwood@pbrc.edu>, Fred Reinhart <fred@research.umass.edu>, Mary Albertson (mary.albertson@stanford.edu) <mary.albertson@stanford.edu>, Michael Waring <mwaring@umich.edu>, Robert Hardy <RHardy@COGR.edu>

"The soul of academic science is being destroyed, one patent at a time." Don't be surprised if this article isn't brought up on Friday: http://www.michaeleisen.org/blog/?p=1981

It ends by blaming Bayh-Dole, recommending that inventions be placed in the public domain. This will be music to KEI's ears.

--

Joseph P. Allen
President
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(W) 740-484-1814
(c) b6
www.allen-assoc.com

From: Eiss, Robert (NIH/FIC) [E] [/O=NIH/OU=EXTERNAL (FYDIBOHF25SPDLT)/CN=RECIPIENTS/CN=B6F003F302BA4FDFB202EE80B0CAE671]
Sent: 6/13/2017 6:33:16 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: Fw: Controversy surrounding ZIKA vaccine development
Attachments: msf_comments_to_fr_notice_re_zika_vaccine_candidate_licensing.pdf; ATT00001.htm; img-511164612-0001.pdf; ATT00002.htm

Sent from my BlackBerry 10 smartphone.

From: Kilmarx, Peter (NIH/FIC) [E]
Sent: Tuesday, June 13, 2017 1:46 PM
To: FIC Division and Office Directors
Subject: Fwd: Controversy surrounding ZIKA vaccine development

May be of interest...

Peter Kilmarx, Deputy Director
Fogarty International Center, NIH
RADM, U.S. Public Health Service

Begin forwarded message:

From: "Lubinski, Christine" <clubinski@idsociety.org>
To: "Global Health Committee" <GlobalHealthCommittee@idsociety.org>
Cc: "Aziz, Rabita" <raziz@idsociety.org>, "McGoodwin, Colin" <CMcGoodwin@idsociety.org>
Subject: Controversy surrounding ZIKA vaccine development

Hello all- Colleagues from the Walter Reed Army Institute for Research reached out to IDSA staff about their concerns about congressional and media attention focused on a potential exclusive license to be granted to Sanofi for one of many Zika vaccine candidates still under development. It appears that widespread concern about drug pricing is spilling over into the vaccine arena and there seems to be little understanding of the vaccine development process not to mention premature pressure to price a vaccine still under development. Colleagues at WRAIR are concerned about the chilling effect this may have on actually getting an efficacious vaccine licensed. I am attaching a letter from MSF and from the governor of Louisiana as well as a couple of press stories about this.

We just wanted to alert this Committee and the Public Health Committee to this issue, since IDSA may be called upon to comment at some point.

https://www.statnews.com/pharmalot/2017/05/17/sanofi-us-army-zika-vaccine/

http://www.huffingtonpost.com/entry/zika-vaccine-sanofi_us_59373298e4b0ce1e7408b9ca?utm_hp_ref=zika

Comments are welcome. Christine

MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

333 Seventh Avenue, 2nd Floor
New York, NY 10001-5004

Tel: (212) 679-6800
Fax: (212) 679-7016

Web: www.doctorswithoutborders.org

For more information, contact: Judit Rius, U.S. manager and legal policy adviser & Jen Reid, advocacy and research officer at judit.rius@newyork.msf.org

To:
Commander, U.S. Army Medical Research and Materiel Command
ATTN: Command Judge Advocate, MCMR-JA, 504 Scott Street
Fort Detrick, MD 21702-5012 USA

Doctors Without Borders/Médecins Sans Frontières (MSF) Comments to the Department of Defense Notice of Grant Intent to an Exclusive License of U.S. Government-Owned Patents on Zika Vaccine

January 23, 2017

Doctors Without Borders/Médecins Sans Frontières (MSF) provides the following comments regarding the Notice from the Department of the Army of the United States Department of Defense *of its intent to grant an exclusive, royalty-bearing, revocable license to pending United States Provisional Patent Application 62/ 343,315, entitled, "Zika Virus Vaccine and Methods of Production" filed May 31, 2016 and an exclusive, royalty-bearing, revocable license to pending United States Provisional Patent Application 62/370,260, entitled, "Zika Vaccine and Methods of Preparation" filed August 3, 2016 to Sanofi Pasteur.* Notice appeared in 81 FR 89087 on Friday, December 9, 2016.

MSF objects to the grant of an exclusive patent license and urges the United States government to consider the negative impact an exclusive agreement will have on the development, affordability and availability of a Zika vaccine, which is urgently needed for people affected by the Zika virus in the United States and worldwide. We ask the U.S. government to consider instead granting an open non-exclusive patent license with appropriate and publicly available terms and conditions to help ensure that further development of this U.S. government funded-technology will prioritize all health needs and ensure sustainable and affordable access of any resulting vaccine.

Overview

MSF is an international medical humanitarian organization working in nearly 70 countries. Every year, MSF vaccinates tens of thousands of children, delivering more than 3.9 million doses of vaccines and immunological products in 2014 alone. We need biomedical innovations that improve medical outcomes and are accessible and affordable, including for prevention and treatment of global health emergencies. We hope to use an effective Zika vaccine in our medical operations in the future. MSF, Ministries of Health and people around the world will only be able to benefit from the U.S. government investment if the resulting vaccine is effective, safe, available, affordable and suitably adapted to the resource-limited settings where most people affected by Zika virus live. Through our work, MSF witnesses the everyday impact of having limited or no access to medicines, diagnostics and vaccines, due to the lack of innovation on essential, suitably adapted and affordable medical tools in the contexts and populations where they are most needed.

We recognize the need to reward innovation and finance research and development (R&D). We thank the U.S. government for its funding and leadership in Zika vaccine research. The acceleration[1] of research on Zika vaccine candidates almost a year after the World Health Organization declared the epidemic a global health emergency is very welcomed.

However, an exclusive license to a single pharmaceutical company is unnecessary to promote innovation and instead has the potential of hindering innovation as well as future access to this promising vaccine candidate. The need for an open public health-driven innovation approach is even more important given that this medical technology has been fully funded and is owned by the United States government. The licensing of this technology should ensure full public return on the public investment that U.S. taxpayers have made and are continuing to make.

A vaccine that is not appropriately developed or a vaccine without appropriate measures to ensure access is insufficient and would be a missed opportunity to make maximal use of limited US government resources. The next step in the Zika vaccine development process, including its licensing and technology transfer strategy, needs to ensure that U.S. government funding and leadership in vaccine R&D results in a vaccine that is effective and accessible for all patients in need in the U.S. and globally, including the most neglected. As the latest Ebola outbreak in West Africa should constantly remind us, diseases have no borders in a globalized world. Without a global research and access strategy for the Zika vaccine, Zika will not be fully stopped.

Exclusive patent licensing is not a necessary or appropriate strategy to further develop this Zika vaccine candidate.

MSF objects to the granting of this exclusive license for development of Zika vaccine candidates for the following reasons:

1. The grant of exclusivity is not a reasonable and necessary incentive to promote innovation and further development of a Zika vaccine.

We agree with comments submitted by Knowledge Ecology International and others[2] that argue that the Army proposal to grant an exclusive license to patents on a Zika vaccine to Sanofi Pasteur (Sanofi) is contrary to the provisions of 35 U.S.C. 209(a)(1). According to U.S. law, the United States government may grant an exclusive or partially exclusive license "only if" the exclusivity is "a reasonable and necessary incentive to call forth the investment capital needed to bring the invention to practical application; or otherwise promote the inventions utilization by the public." In other words, the U.S. government cannot grant exclusive licenses in cases where the exclusive rights are not reasonable and necessary for the practical application and utilization of the invention.

Before an exclusive license is granted, Sanofi or any other potential recipient of an exclusive license and the U.S. Army have the burden of proving that these exclusive rights are necessary. Pharmaceutical companies usually argue that exclusivity is necessary to recoup investments and risk associated with the research and development process, as well the opportunity cost to work on a given technology, but we argue that this exclusivity is unnecessary to promote innovation and the further development of the vaccine candidate given:

a. The significant funding and resources that the U.S. government has already dedicated to this vaccine candidate, including more than $40 million in BARDA grant funding to Sanofi.[3]

b. Sanofi and any other vaccine developer that further develops this vaccine candidate are also eligible to receive additional funding, incentives and subsidies from the U.S. government, including the likely lucrative Food and Drug Administration (FDA) Priority Review Voucher (PRV) for neglected diseases, without any product access conditions attached, if a vaccine is successfully registered with the FDA[4], as well as potentially the different tax credits and exclusivities attached to an orphan drug designation. The FDA voucher itself has been valued on the open market at at least 350 million USD through recent reported transactions.

c. Sanofi and other vaccine developers may also receive other resources provided by other countries. For example, the funds and resources that will be made available to accelerate vaccine development for emerging infectious diseases with the recently launched Coalition for Epidemic Preparedness Innovations (CEPI) that multiple governments, philanthropies like the Bill & Melinda Gates Foundation and the Wellcome Trust, and MSF are members of.

d. There is no publicly available information on the investment that Sanofi has made or will need to make to complete development of this vaccine. The financial risk and investment that Sanofi will need to make is limited and predictable, but the potential profitability is considerable. There is an expected profitable commercial market for this vaccine that will provide appropriate incentives for recovering any potential additional investment that Sanofi or any other vaccine developers may need to make to further develop this technology.

2. The grant of patent exclusivity can hinder innovation for Zika vaccines and doesn't allow research strategies that promote collaboration and focus on neglected medical needs.

The grant of exclusive rights in the US government-owned patents is not the best tool to promote innovation and can hinder innovative efforts on Zika vaccine development. Even where government funding does lead to important advances in biomedical innovation, these investments still do not necessarily lead to effective prioritization of further R&D and successful outcomes driven by patients and public health needs if the appropriate licensing and technology strategy is not pursued.

a. An exclusive license will give Sanofi a monopoly in the research, manufacturing and sale of the technology and will allow Sanofi to exclude competition in the clinical development as well as in the manufacturing and pricing of this technology.

b. The grant of exclusivity does not ensure that the Zika vaccine development process will target the populations most in need. Sanofi will be allowed to pursue research strategies to maximize use of the vaccine candidate in profitable markets, like the U.S. or the travel market, limiting or excluding clinical development of competing research agendas that should include a broader and diverse geographical scope to ensure any resulting vaccine is effective and useful in the full range of populations who may need this vaccine, including neglected patients in Africa and other neglected regions.[5]

c. The grant of exclusivity does not ensure that a vaccine will be developed or that it will adhere to a timely development process. The recent announcement on promising results of clinical trials of rVSV Ebola vaccine that MSF supported shows the importance of government funding and leadership for vaccine development. It also shows how the Canadian government's exclusive licensing was unnecessary and tragically delayed urgently needed innovation. It was thanks to initial studies at a Canadian government laboratory that the VSV-EBOV vaccine was confirmed as potentially effective against Ebola. Despite the fact that the government licensed this vaccine to a U.S. company, NewLink, four years before the West African Ebola outbreak, the project stalled and the vaccine was not made available to people at risk for more than five years. If at least Phase

I clinical trials had been conducted prior to the most recent outbreak, the vaccine could have been deployed during the emergency and potentially helped save lives. This wasted opportunity and failure to advance the vaccine's development nevertheless netted NewLink more than $63.5M profit when they sold the rights to pharmaceutical company Merck during the most critical phase of the outbreak. A non-exclusive license could have allowed the Canadian government, either prior to or during the outbreak, to take more decisive action to encourage or require the timely testing and development of the vaccine.

3. An exclusive license can be a barrier to ensuring a Zika vaccine will be available and affordable to all who need it.

The high price of vaccines is already a key medical and operational challenge for MSF and many governments. By 2014 the price to fully vaccinate a child in the poorest countries of the world was 68 times more expensive[6] than it was in 2001. The price in other countries is even higher. Many countries, especially countries considered middle-income economies, are often unable to afford new high-priced vaccines that prevent countless deaths from vaccine-preventable diseases such as childhood pneumonia.

Before granting a license on U.S. government-owned rights, the U.S. government should ensure that the license will ensure that the "benefits" of the invention will be "available to the public on reasonable terms," a requirement of 35 U.S.C. §201(f). Granting an exclusive license to a vaccine manufacturer will not only fail to ensure any resulting vaccine is available on reasonable terms, but can also become a significant barrier to the future availability and affordability of the vaccine.

As the vaccine development has been publicly financed by the U.S. government, the price of any resulting vaccine should be closely aligned with production costs. Yet, an exclusive license to Sanofi will allow the company to charge high prices based on what their targeted markets will bear regardless of actual costs. Based on our experience, leaving these decisions exclusively to a pharmaceutical company may not lead to appropriate public health outcomes. We hope Sanofi commits to and implements an appropriate access and manufacturing strategy, but it is relevant for the U.S. government to know that when left to decide strategy without government oversight, Sanofi has failed previously and currently to ensure uninterrupted manufacturing, supply and affordability of essential medical tools for which they are the sole supplier. For example, Sanofi's pricing strategies for its inactivated polio vaccine[7] and dengue vaccine[8] are a barrier to access for many middle-income countries.

While MSF continues to be challenged by high prices of medical tools, we know that high prices are avoidable and affordable innovation is possible. In 2001, high prices left MSF limited in our ability to save the lives of people living with HIV. At the time pharmaceutical companies charged MSF, governments and patients an astronomical US $10,000 per person, per year for antiretroviral medicines used to treat HIV. This meant that MSF and governments, in the face of thousands of people dying daily from AIDS-related illnesses, could only provide treatment to a very limited number of people. In response, affected governments and civil society applied legal safeguards to remove patent barriers and foster generic competition. HIV treatment costs fell, virtually overnight, to one US dollar a day per person.[9] As a result of competition among generic medicines producers, prices for first-line HIV medicines have continued to fall and today more than 18 million people receive treatment,[10] including through U.S. government-funded programs such as the President's Emergency Plan For AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund). In 2012, generics accounted for 96 percent of all treatments purchased by donor-funded programs such as the Global Fund.[11]

An exclusive license will also be barrier to competition in the manufacturing and supply of the technology, as it will allow Sanofi to exclude other manufacturers from producing and selling the technology. Promoting competition is the best tool to ensure affordability as well as ensuring sufficient manufacturing and supply of any resulting vaccine. MSF and patients have repeatedly experienced the consequences of what happens when a single supplier discontinues manufacturing of an effective and needed product for conditions affecting neglected populations. For example, in 2010, due to limited profitability, Sanofi decided to stop manufacturing an important antivenom to treat deadly snake bites. The company did not reveal this decision until 2013, resulting in a worldwide supply shortage of a critical antivenom before a replacement product can be launched.[12]

A better way to promote U.S. government funded innovation: open non-exclusive licenses with terms and safeguards for patient-driven innovation and future affordable access

An exclusive license fails to address the need for an innovation strategy that put the needs of all patients and vaccine providers at the center of the biomedical innovation system. Instead, MSF recommends that the U.S. government consider an open licensing and technology transfer strategy to allow Sanofi and a variety of vaccine developers and researchers to test and further develop this vaccine, promoting a variety of scientific, research, development, business and delivery approaches. The licensing of this technology should include the creation of terms and conditions that will act as safeguards to ensure that the development will be patient-driven and that any resulting vaccine will be safe, effective, appropriately available and affordable to all people in need. We also recommend that the U.S. government make the terms and conditions of the license publicly available to allow for appropriate review, accountability and implementation of the safeguards created.

Granting an open non-exclusive license with the appropriate terms and conditions will have at least the following positive public health impact:

1. An open license can help promote timely development of the vaccine candidate.

An open, non-exclusive license not only ensures that multiple companies can move towards developing the product, but can ensure that if one company fails to meet milestones or advance development, the patent holder (the US government) can move on to others and not have their hands tied. A non-exclusive license allows several vaccine developers to pursue different research, regulatory and development strategies of the vaccine candidate, and also can reduce the negative health impact of research stalled or delayed by a single researcher strategy. For example, in the case of the rVSV Ebola vaccine highlighted above, had the Canadian government granted an open license, governments and medical service providers such as MSF would not have been dependent on the development timeline of only one company.

2. An open license will allow interested companies to test the safety and efficacy of the vaccine candidate in a variety of populations and contexts.

An open license allows several companies and vaccine researchers to test the effectiveness and safety of the technology in a variety of settings, including pursuing research strategies that target the needs of neglected populations due to expectation of limited profitability and/or knowledge gaps on Zika epidemiology in Africa.

3. An open license will help ensure stable supply.

An open license allows several companies to manufacture a resulting vaccine and reduces the public health liability created by a single manufacturer that decides to stop manufacturing or is not able to meet the global demand of a successfully developed Zika vaccine.

4. An open license will help ensure affordable access.

An open license may facilitate the emergence of competition in the manufacturing and supply of Zika vaccines, which is ultimately the best tool to promote affordability.

U.S. government can lead the way on creating new models for research and development for essential medical tools

The reliance on the creation and granting of exclusivities to pharmaceutical companies in R&D of essential medical technologies is a flawed paradigm for funding and promoting innovation. This often leads to limited access while failing to stimulate open and patient-driven innovation. It is even less rational when the United States is already funding and de-risking the development of the medical technology as is the case with the Zika vaccine.

New approaches are needed not only to avoid US taxpayers paying twice[13] – first by paying a significant percentage of the R&D costs and second by paying high prices – but also to ensure that the vaccine development and manufacturing process will be public health-driven and benefit all in need, especially for essential medical tools like vaccines needed for emergencies and epidemics.

MSF has for years raised the alarm about the challenges of high prices and need for new incentives to promote innovation that do not rely on monopolies and exclusivities. In our experience, both as a medical provider and funder of innovation,[14] competition and open access to essential medical technologies is a useful tool to reduce prices and promote supply security and therefore increase access to resulting technologies. MSF recently published a report on biomedical innovation, "Lives on the Edge: Time to align medical research and development with people's health needs,"[15] that provides an overview of some the challenges with the current innovation system and our proposals on steps governments need to take to improve it.

New approaches to promote medical innovation, including approaches that MSF and others have supported, are demonstrating that affordable and accessible medical breakthroughs are possible. This is particularly true when intellectual property is openly pooled, like with the UNITAID-Medicines Patent Pool – which the US National Institutes of Health was the first to join, to promote competition in the HIV/AIDS drug development[16] – and when incentives break the link between the cost of R&D and the price and sale of the end product.

There are ongoing efforts in international fora to consider how this could be achieved, including in the commitments made by the United States and other governments on new models for biomedical innovation that de-link R&D costs from prices in recent years at the World Health Assembly following the Report of the Consultative Expert Working Group on R&D Financing and Development (CEWG report) and most recently through the 2016 UN Political Declaration on Antimicrobial Resistance. In the same direction, the recently released report of the UN Secretary General's High Level Panel on Access to Medicines made a variety of recommendations,[17] including increasing transparency and reforming incentives for innovation, especially for the licensing of publicly funded research.

Conclusion

At a time when the high price of life-saving medical tools, including hepatitis drugs, biologics and vaccines, is becoming a barrier to effective medical care worldwide and medicines are being rationed because of high prices in the U.S. and around the world, it is very concerning to see the U.S. government considering locking in a development deal that will limit innovation and will not safeguard affordable access to the resulting vaccine. Instead of creating new exclusivities for pharmaceutical companies by giving away exclusive rights on publicly funded innovation, the U.S. government should pursue R&D strategies that promote open and collaborative innovation and ensure affordable access to resulting products.

---

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[2] Comments by KEI and others. An exclusive license to patents on a new Zika vaccine to Sanofi is contrary to the provisions of 35 U.S.C. 209(a)(1). Submitted 12 January 2017. Available from: http://keionline.org/sites/default/files/Zika-12Jan2016-KEI-AFSCME-PFAM-UAEM-BAKER-35USC209a1.pdf

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[8] Coconuts Manila. DOH: We can't afford to give free dengue vaccine to everyone. 22 February 2016. Available from http://manila.coconuts.co/2016/02/22/doh-we-cant-afford-give-free-dengue-vaccine-everyone

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[12] MSF. Snakebite: How Sanofi slithered its way out of the neglected antivenom market. July 2015. Available from: *https://www.msfaccess.org/sites/default/files/NTDs_Brief_FavAfrique_ENG_2015.pdf*

[13] An exclusive license will undermine existing United States domestic and global commitments towards the fight against zika. The Congressionally approved Zika funding totals at least $1.1 billion in 2016. Source: The Status of Funding for Zika: The President's Request, Congressional Proposals, & Final Funding - http://kff.org/global-health-policy/issue-brief/the-status-of-funding-for-zika-the-presidents-request-congressional-proposals-final-funding/

[14] See for example, http://www.dndi.org/wp-content/uploads/2009/03/DNDi_Modelpaper_2013.pdf and MSF's proposal for a better model for TB R&D regime development: http://www.msfaccess.org/spotlight-on/3p-project-new-approach-developing-better-treatments-tb

[15] MSF. Lives on the Edge: Time to align medical research and development with people's health needs. May 2016. Available from: http://www.msfaccess.org/content/report-lives-edge-time-align-medical-research-and-development-people%E2%80%99s-health-needs

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Office of the Governor
State of Louisiana

JOHN BEL EDWARDS
GOVERNOR

P.O. BOX 94004
BATON ROUGE, LOUISIANA 70804-9004
(225) 342-7015
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May 10, 2017

Robert M. Speer
Acting Secretary of the Army
101 Army Pentagon
Washington, DC 20310-0101

Dear Mr. Speer,

As Governor of the State of Louisiana, I write to express my serious concern about the Department of Defense's proposed exclusive license of patents on a Zika vaccine to Sanofi, particularly if the license does not address the pricing of the vaccine to U.S. residents.

Louisiana remains one of the Gulf states most likely to be affected in the event that the Zika virus continues to spread. A decision to give one company, Sanofi, a monopoly, without any constraints on the price for the vaccine, could cripple state budgets and threaten public health in the event of local Zika transmission. As many as 540,000 Louisiana residents on Medicaid alone could benefit from an effective Zika vaccine, but all my constituents deserve access in the event of local transmission. I am concerned that an unaffordable Zika vaccine will unnecessarily expose our state's most vulnerable citizens, our babies, to risk for serious lifelong complications of preventable Zika infection.

It is my understanding that considerable federal support has gone into creating the vaccine, including federally-funded clinical trials, a $43 million BARDA grant to Sanofi for Phase II trials, with the option for an additional $130 million in funding for the later trials if needed for the vaccine's approval by the FDA. Sanofi would also be eligible for a valuable priority review voucher, worth millions of dollars, and possibly benefit from several years of exclusive rights on the data from the clinical trials the U.S. government has funded. The extent of public investment in the development of the vaccine calls into question the need for an exclusive license, and it certainly provides a compelling reason to ask questions about the price of the vaccine now, before a license is signed, rather than after a monopoly has been granted.

Furthermore, because the vaccine in question is the Zika Purified Inactivated Virus (ZPIV) and makes use of the inactivated virus to produce an immune response, it may have added benefits and value as a booster vaccination to DNA Zika vaccines. Preliminary studies by NIAID found that the ZPIV induced antibodies that neutralized the virus and protected animals from disease when they were challenged with Zika.

I am concerned that the Department of Defense has yet to address concerns about pricing and affordability for the vaccine, despite requests from nearly a dozen non-governmental organizations representing patient interests. In April 2017 the Department of Justice ordered Sanofi to repay nearly $20 million in overcharges to the Department of Veterans Affairs. Sanofi is known to charge U.S. residents far more than residents of other industrialized countries for other medications, such as Sanofi's multiple sclerosis drug Aubagio (teriflunomide).

We believe our interests would be better served by avoiding the grant of an exclusive license on the Army's Zika patents. Barring that, U.S. residents, particularly those that I represent in Louisiana, deserve assurances that the vaccine will be affordable to people who have already paid for most of the research and development costs.

No one should have to worry about their child being born with microcephaly or other birth defects, and certainly no one should have to face that frightening prospect simply because the vaccine is unaffordable. Louisiana taxpayers have already paid once for this invention, and it is reasonable to expect that the Department of Defense at minimum ensure that our residents pay reasonable prices on the other end.

Sincerely,

John Bel Edwards
Governor

cc: Barry Datlof

From: Petrik, Amy (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C4EC05A179F04067B61F20605E911E7C-PETRIKA]
Sent: 12/13/2017 7:57:38 PM
To: Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Salata, Carol (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f98ca6a1f9fc4cfdbbf4036ca8cbace4-csalata]; Feliccia, Vincent (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f3a54860cb941c1abe1df786e478e00-vfeliccia]
Subject: RE: Final Determination for A-419-2017 for review
Attachments: Re: Proposed grant of an exclusive license to Zika Vaccine; KEI, MSF Comments Relating to Prospective Grant of Exclusive Patent License: DNA-Based Vaccine for Prevention of Zika Virus Infection

Yes, here are the two sets of comments from KEI and from KEI and MSF.

From: Berkley, Dale (NIH/OD) [E]
Sent: Wednesday, December 13, 2017 2:52 PM
To: Petrik, Amy (NIH/NIAID) [E] <amy.petrik@nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Salata, Carol (NIH/NIAID) [E] <csalata@niaid.nih.gov>; Feliccia, Vincent (NIH/NIAID) [E] <vfeliccia@niaid.nih.gov>
Subject: RE: Final Determination for A-419-2017 for review

Amy—could you provide us with the letter from KEI?

Thanks, Dale

Dale D. Berkley, Ph.D., J.D.
Office of the General Counsel, PHD, NIH Branch
Bldg. 31, Rm. 47
Bethesda, MD 20892
301-496-6043
301-402-2528(Fax)
This message is intended for the exclusive use of the recipient(s) named above. It may contain information that is PROTECTED or PRIVILEGED, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information.

From: Petrik, Amy (NIH/NIAID) [E]
Sent: Wednesday, December 13, 2017 2:30 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>
Cc: Salata, Carol (NIH/NIAID) [E] <csalata@niaid.nih.gov>; Feliccia, Vincent (NIH/NIAID) [E] <vfeliccia@niaid.nih.gov>
Subject: Final Determination for A-419-2017 for review

Hi Mark and Dale,

I've drafted the attached final determination for the proposed PaxVax exclusive license to the NIAID Zika vaccine technology, with input from my TTIPO colleagues.

Would you each, please, review and let me know if you have any suggestions/edits to improve it?

If you have any questions, please don't hesitate to call.
Thanks,
Amy

Amy F. Petrik, Ph.D.
Technology Transfer and Patent Specialist

Technology Transfer and Intellectual Property Office
National Institute of Allergy and Infectious Diseases
National Institutes of Health, HHS

5601 Fishers Lane
Suite 2G
Rockville, MD 20892-9804
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From: Kim Treanor [kim.treanor@keionline.org]
Sent: 11/7/2017 7:36:01 PM
To: Petrik, Amy (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c4ec05a179f04067b61f20605e911e7c-petrika]
Subject: Re: Proposed grant of an exclusive license to Zika Vaccine

Dear Dr. Petrik,

I was hoping to follow up on the below. Also, can you confirm that the subject of the proposed exclusive license is: VRC-ZKADNA090-00-VP, ZIKVwt (VRC 320), currently in Phase II trials?
http://bciq.biocentury.com/products/zikvwt

Best regards,
Kim

On Wed, Oct 25, 2017 at 2:53 PM, Kim Treanor <kim.treanor@keionline.org> wrote:

> Dear Dr. Petrik,
>
> I am writing in regards to the proposed grant of an exclusive patent license of a DNA-based vaccine for prevention of Zika virus infection to PaxVax Inc, as referenced in 82 FR 47537. As a part of this licensing agreement or separately from it, if the exclusive license is granted, will the NIAID or another division of the NIH also provide PaxVax with grants or financial support to conduct clinical trials on this vaccine candidate? PaxVax reports on their website that they have a Zika vaccine candidate in the pipeline which they are working on with the CDC. Do you know if this vaccine candidate has received any financial support from NIAID or another division of the NIH?
>
> Thank you for your assistance.
>
> Best regards,
> Kim
>
> --
>
> Kim Treanor
> Knowledge Ecology International
> kim.treanor@keionline.org
> tel.: +1.202.332.2670

--

Kim Treanor
Knowledge Ecology International

kim.treanor@keionline.org
tel.: +1.202.332.2670

From: Andrew S. Goldman [andrew.goldman@keionline.org]
Sent: 11/13/2017 8:59:27 PM
To: Petrik, Amy (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c4ec05a179f04067b61f20605e911e7c-petrika]
CC: Jamie Love [james.love@keionline.org]; Kim Treanor [kim.treanor@keionline.org]; Jennifer Reid [Jennifer.Reid@newyork.msf.org]
Subject: KEI, MSF Comments Relating to Prospective Grant of Exclusive Patent License: DNA-Based Vaccine for Prevention of Zika Virus Infection
Attachments: KEI_PaxVax_111317.pdf; KEI MSF NIH Zika Vaccine License Comments November 2017.pdf

Dear Dr. Petrik:

On behalf of Knowledge Ecology International (KEI) and Médecins Sans Frontières (MSF), please see the two attached documents:

(1) Comments submitted on behalf of both KEI and MSF on the proposed exclusive license of a Zika vaccine referred to in FR Vol. 82, No. 196 on October 12, 2017; and
(2) Additional comments of KEI on potential conflicts of interest that create a compelling need for increased transparency with regard to the proposed license, and on additional proposals to limit the scope of exclusive rights.

If you have any questions with regard to these two documents, please let me know.

Sincerely,

Andrew S. Goldman
Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
www.keionline.org

From: Mascola, John (NIH/VRC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F78B40A596B4CA4A2850A429D1AE3F2-JMASCOLA]
Sent: 9/12/2017 3:24:35 PM
To: Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]; Billet, Courtney (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7605eeb349ac41138b32fe3978e3986d-billetc]
CC: Eisinger, Robert (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bad2a8c45514ee48985880de66674ad-eisinger]; Stover, Kathy (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c82722674ba14c2f969bd50dfa6a7af4-stoverk]; Haskins, Melinda (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545e01141619453bb4fc1dcde6c45887-haskinsm]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Paules, Catharine (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e3435aa00e54d419df3e535016c19fa-paulesci]
Subject: RE: Zika vax -- talking pts and website language

As further point of education for us: b5

b5

From: Marston, Hilary (NIH/NIAID) [E]
Sent: Tuesday, September 12, 2017 11:12 AM
To: Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Paules, Catharine (NIH/NIAID) [E] <catharine.paules@nih.gov>
Subject: RE: Zika vax -- talking pts and website language

b5

b5 KEI and others have used this "most non-exclusive" point to argue against exclusive licenses (see excerpt below from https://www.keionline.org/sites/default/files/Senate-Letter-to-Sanofi-re-Zika-Vaccine-Army-Pricing.pdf). Is the 95% correct? And what does that 95% actually represent (e.g., licenses to techniques, reagents, etc.). Again – not needed for today, but possibly important for interviews.

b5

From: Mascola, John (NIH/VRC) [E]
Sent: Tuesday, September 12, 2017 10:57 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: Zika vax -- talking pts and website language

Want to highlight Mark's comment on following text:

b5

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, September 12, 2017 10:37 AM
To: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>; Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: Zika vax -- talking pts and website language

I have a few comments on the Talking Points. THx

From: Mowatt, Michael (NIH/NIAID) [E]
Sent: Tuesday, September 12, 2017 10:07 AM
To: Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>; Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>
Subject: RE: Zika vax -- talking pts and website language

Proposed changes tracked and highlighted in yellow.

b5 See my comment.

b5

From: Billet, Courtney (NIH/NIAID) [E]
Sent: Tuesday, September 12, 2017 9:54 AM
To: Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: Zika vax -- talking pts and website language

Ok, thanks

From: Mascola, John (NIH/VRC) [E]
Sent: Tuesday, September 12, 2017 9:53 AM
To: Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: Zika vax -- talking pts and website language

b5

John

From: Billet, Courtney (NIH/NIAID) [E]
Sent: Tuesday, September 12, 2017 9:40 AM
To: Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: Zika vax -- talking pts and website language

The talking points document itself does not get distributed publicly. This is an internal planning/preparation document essentially getting everyone on the same page re what our SME's will say when they talk about this with reporters etc.

Thanks for whatever you can do in the time you have. Believe it or not they are already pestering me for it!

From: Mascola, John (NIH/VRC) [E]
Sent: Tuesday, September 12, 2017 9:28 AM
To: Billet, Courtney (NIH/NIAID) [E] <billetc@niaid.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: RE: Zika vax -- talking pts and website language

Talking points are public document – correct? If so, they need edits – I have 15 min before chairing workshop – will see what I can do.

John

From: Billet, Courtney (NIH/NIAID) [E]
Sent: Tuesday, September 12, 2017 9:13 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Mascola, John (NIH/VRC) [E] <jmascola@mail.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Eisinger, Robert (NIH/NIAID) [E] <robert.eisinger@nih.gov>; Stover, Kathy (NIH/NIAID) [E] <kathy.stover@nih.gov>; Haskins, Melinda (NIH/NIAID) [E] <haskinsm@mail.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>
Subject: FW: Zika vax -- talking pts and website language

HI all -- Edits from HHS on both documents. Would appreciate your review and response. Hope to send ASF a final for one last review by noon. Thanks

---

From: Baden, Elizabeth (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BADENEM]
Sent: 1/27/2017 3:50:38 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: BRAIN record - Drug Pricing
Attachments: Drug Pricing.docx

Hi Mark,

I checked with Chanel, and she was working on the Gene and Germline Editing Technology record. They added a section about IP to part of that record, so I think that's what she was consulting you about.

It looks like you actually updated the Drug Pricing record on Dec. 1st. I've attached it as a Word document here. Could you review and see if any other updates are needed? Also, the overall length of the record should be shorter (about 7 pages as opposed to the 10 pages it is currently). If you have any suggestions for what to shorten or remove, that would be helpful. The first section, Key Points, also needs to be limited to 150 words and contain the most recent, important information that might be needed in a hearing.

Please feel free to make any changes directly in the BRAIN database, or, if it's easier, then just edit the Word document and I can put them in.

Best,
Elizabeth

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Thursday, January 26, 2017 9:48 PM
To: Baden, Elizabeth (NIH/OD) [E] <badenem@od.nih.gov>
Subject: Re: BRAIN record - Drug Pricing

I thought I had finished it last month, then Chanel came to me with something that had been changed significantly I made some edits for her and understood she was going to input them. I am very confused

Sent from my iPhone

On Jan 26, 2017, at 8:33 PM, Baden, Elizabeth (NIH/OD) [E] <badenem@od.nih.gov> wrote:

> Hi Mark,
>
> You are listed as the OSP author for the BRAIN record on Drug Pricing. The review process has commenced, so I was wondering if you have an estimate of when the record might be ready to upload into the system. If you have any questions, please let me know.
>
> Best,
> Elizabeth

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